EXHIBIT A

MEDIMMUNE, INC., Plaintiff–Appellant, v. CENTOCOR, INC., Defendant–Appellee, and THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, Defendants–Appellees.

04–1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2005 U.S. App. LEXIS 9965

June 1, 2005, Decided

PRIOR HISTORY: [*1] Appealed from: United States District Court for the District of Maryland. Judge Alexander Williams, Jr. MedImmune, Inc. v. Centocor, Inc., 271 F. Supp. 2d 762, 2003 U.S. Dist. LEXIS 12592 (D. Md., 2003)

AFFIRMED.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff patent sublicensee appealed from a decision of the United States District Court for the District of Maryland that dismissed its declaratory judgment action against defendants, the patent licensee et al. The sublicensee sought to have U.S. Patent No. 5,807,715 declared invalid. The court dismissed the action because no actual controversy existed as required under the Declaratory Judgment Act, 28 U.S.C.S. § 2201(a).

OVERVIEW: Any controversy that may have existed between the sublicensee and the licensee prior to and during their various negotiations vanished when the sublicensee executed the license agreement, which was a covenant by the licensee not to sue. It was undisputed that the sublicensee continued to pay timely royalties and was not otherwise in breach of the agreement. Because the license agreement was in place and the sublicensee was in compliance with the terms of the agreement, the sublicensee could not have been under a reasonable apprehension that it would face an infringement suit. The fact that the licensee did in fact sue the sublicensee after the sublicensee filed its declaratory judgment suit did not alter the analysis because the presence or absence of a case or controversy was based on facts at the time the complaint was filed; later events could not create jurisdiction where none existed at the time of filing. Finally, the appellate court rejected the sublicensee's contention that the decision on which the district court relied in finding that no controversy existed was contrary to circuit and United States Supreme Court precedent.

OUTCOME: The appellate court affirmed the decision of the district court.

CORE TERMS: patent, licensee, declaratory judgment, royalty, license, license agreement, actual controversy, licensor, apprehension, licensed, Declaratory Judgment Act, infringement, invalidity, invalid, paying, negotiations, sublicense, unenforceable, declaration, infringer, covenant, infringe, patentee, urges, subject matter jurisdiction, declaratory judgment action, lack of jurisdiction, good standing, justiciability, precedential

LexisNexis(TM) Headnotes

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN1] Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non–infringement and/or invalidity is governed by Federal Circuit law.

Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN2] The determination of whether an actual controversy exists under the Declaratory Judgment Act in a patent case is a question of law that the United States Court of Appeals for the Federal Circuit reviews de novo.

Civil Procedure > Justiciability > Case or Controversy
Constitutional Law > The Judiciary > Case or Controversy > Advisory Opinions
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions
[HN3]

The Declaratory Judgment Act provides that in a case of actual controversy within its jurisdiction a court may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. 28 U.S.C.S. § 2201(a). Paralleling U.S. Const. art. III, the Act requires an actual controversy between the par ties before a federal court may exercise jurisdiction over an action for a declaratory judgment. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN4] In patent cases, to keep watch over the subtle line between an "abstract question" and a controversy contemplated by the Declaratory Judgment Act, an inquiry has been formulated that focuses on the conduct of both the patentee and the accused infringer. When a potential infringer seeks declaratory relief in the absence of a lawsuit by the patentee, there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions
Patent Law > Ownership > Conveyances > Licenses

[HN5] In determining where there is an actual case or controversy for purposes of the Declaratory Judgment Act in the context of a patent case, where there is a license, unless materially breached, obliterates any reasonable apprehension of a lawsuit, and once the licensor and licensee formed the license, an enforceable covenant not to sue, the events that led to the formation of the license became irrelevant.

Governments > Courts > Judicial Precedents

[HN6] A decision that fails to consider United States Supreme Court precedent does not control if an appellate court determines that a prior panel would have reached a different conclusion if it had considered controlling precedent.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN7] The United States Court of Appeals for the Federal Circuit has twice rejected the idea that the United States Supreme Court's decision in Cardinal Chemical was meant to alter how a federal trial court determines whether a case or controversy exists over a declaratory judgment suit. Cardinal Chemical does not revolutionize the justiciability of declaratory judgment actions attacking a patent's validity and nothing in Cardinal undermines the Federal Circuit's decisions on declaratory justiciability at the trial court level. The Supreme Court's decision in Cardinal Chemical is limited to the specific facts of that case.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > General Overview
Patent Law > Ownership > Conveyances > Licenses

[HN8] Although the United States Supreme Court's decision in Lear held that a licensee is not estopped from challenging the validity of a licensed patent, Lear left unresolved the question when a federal court has jurisdiction of a licensee's claim of patent invalidity. In other words, the fact that a party is not estopped from making an argument does not mean that federal courts have jurisdiction to entertain that argument in all circumstances.

Civil Procedure > Justiciability > Case or Controversy

[HN9] The presence or absence of a case or controversy is based on facts at the time the complaint is filed. Later events may not create jurisdiction where none exist at the time of filing. Rather, the presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration is filed.

Governments > Courts > Judicial Precedents

[HN10] Although a three–judge panel of the United States Court of Appeals for the Federal Circuit may not overrule a precedential decision of a previous panel, it may recommend en banc review of the decision. Fed. Cir. R. 35(2)(a).

COUNSEL: Harvey Kurzweil, Dewey Ballantine LLP, of New York, New York, argued for plaintiff–appellant. With him on the brief were Aldo A. Badini and Henry J. Ricardo. Of counsel on the brief was Elliot M. Olstein, Carella Byrne Bain Gilfillan Cecchi Stewart & Olstein, of Roseland, New Jersey.

Teresa M. Corbin, Howrey Simon Arnold & White, LLP, of San Francisco, of Los Angeles, California, argued for defendants–appellees. With her on the brief was Jennifer A. Sklenar. Of counsel was Jayna R. Whitt, of Menlo Park, California. Of counsel on the brief were John C. Dougherty, Natalie F. Zaidman, and Sonia Cho, DLA Piper Rudnick Gray Cary US LLP, of Baltimore, Maryland.

JUDGES: Before SCHALL, BRYSON, and GAJARSA, Circuit Judges.

OPINIONBY: SCHALL

OPINION: SCHALL, Circuit Judge.

MedImmune, Inc. ("MedImmune") appeals from the final decision of the United States District Court for the District of Maryland that dismissed, for lack of subject matter jurisdiction, MedImmune's declaratory judgment action against Centocor, Inc. ("Centocor"), the trustees of Columbia University in New York [*2] City, and the Board of Trustees of the Leland Stanford Junior University in California. In its suit, MedImmune sought to have U.S. Patent No. 5,807,715 ("the '715 patent") declared invalid and/or unenforceable. The court dismissed the action after it determined that MedImmune had failed to establish that an actual controversy existed between it and Centocor, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). MedImmune, Inc. v. Centocor, Inc., No. AW–02–1135 (D. Md. June 17, 2004). We affirm.

BACKGROUND

I.

The '715 patent is titled "Methods and Transformed Mammalian Lymphocytic Cells for Producing Functional Antigen-Binding Protein Including Chimeric Immunoglobulin and Fragments." Columbia University and Leland Stanford Junior University are the assignees of the '715 patent. Centocor is the exclusive licensee of the patent, with the right to sublicense the patent to others.

The '715 patent issued in September of 1998. In a May 1999 letter, Centocor offered MedImmune a sublicense under the patent to cover MedImmune's Synagis (R) product. In August of 1999, MedImmune responded to Centocor's letter. In its response, MedImmune stated that [*3] it did not agree that Synagis (R) was covered by the '715 patent, and it indicated that it would not take a license.

In May of 2000, representatives from Centocor and MedImmune began license negotiations. The negotiations spanned several months. In these negotiations, MedImmune took the position that Synagis (R) did not infringe the '715 patent, that the patent was invalid and, alternatively, that MedImmune could design around the '715 patent. MedImmune claims that "facing mounting pressure and fearing an imminent infringement suit," it finally concluded a sublicense agreement with Centocor. The agreement was executed on December 29, 2000. Thereafter, MedImmune began paying royalties on Synagis (R) under the agreement. It is undisputed that MedImmune continues to make timely royalty payments and is not otherwise in breach of the license agreement.

After concluding the license agreement, MedImmune asserted to Centocor that it did not infringe the '715 patent and that the patent was invalid and/or unenforceable. In response, Centocor told MedImmune that it expected MedImmune to continue to adhere to its license obligations.

II.

In April of 2002, MedImmune filed the present declaratory [*4] judgment suit in the District of Maryland, seeking a declaration that it owes no royalties under the license agreement with Centocor and that the '715 patent is invalid and/or unenforceable. Shortly thereafter, Centocor and the universities filed what they characterize as a "mirror-image" declaratory judgment suit against MedImmune in the Northern District of California. In their suit, Centocor and the universities alleged that, in view of MedImmune's suit in Maryland, a case or controversy existed between them and MedImmune. They sought a declaratory judgment that the '715 patent is valid and enforceable, and that MedImmune's manufacture and sale of Synagis (R) infringes the patent.

The Maryland district court granted Centocor and the universities' motion to dismiss for lack of jurisdiction. Relying on Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004), the court determined that MedImmune had failed to establish that an actual controversy existed between it and Centocor, as required under 28 U.S.C. § 2201(a). Centocor and the universities' suit in the Northern District of California was also dismissed, on the ground that there [*5] was "no actual controversy to satisfy the Declaratory Judgment Act" in light of the Maryland suit.

MedImmune timely appeals the decision of the Maryland district court dismissing its suit. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

ANALYSIS

I.

[HN1] Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law. Minn. Mining & Mfg. Co. v. Norton Co., 929 F.2d 670, 672 (Fed. Cir. 1991); Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 954 n. 3 (Fed. Cir. 1987). [HN2] The determination of whether an actual controversy exists under the Declaratory Judgment Act in a patent case is a question of law that we review de novo. Vanguard Research, Inc. v. PEAT, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002).

[HN3] The Declaratory Judgment Act provides that "in a case of actual controversy within its jurisdiction ... [a court] may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." [*6] 28 U.S.C. § 2201(a). Paralleling Article III of the Constitution, the Act "requires an actual controversy between the par ties before a federal court may exercise jurisdiction over an action for a declaratory judgment." Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1331 (Fed. Cir. 2005) (quoting EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996)). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273, 85 L. Ed. 826, 61 S. Ct. 510 (1941).

[HN4] To keep watch over the subtle line between an "abstract question" and "a controversy contemplated by the Declaratory Judgment Act," id., an inquiry has been formulated that focuses on the conduct of both the patentee and the accused infringer. When a potential infringer seeks

declaratory relief in the absence of a lawsuit by the patentee, there must be both (1) a reasonable apprehension on [*7] the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. Teva, 395 F.3d at 1330; Gen-Probe, 359 F.3d at 1380; EMC Corp., 89 F.3d at 811.

II.

As noted above, the district court relied on our decision in Gen-Probe to dismiss MedImmune's declaratory judgment suit for lack of Article III jurisdiction. In Gen-Probe, we considered the case of a licensee in good standing who sought a declaratory judgment that it was not infringing the licensed patent, and that the licensed patent was invalid. 359 F.3d at 1377. The licensee sought a declaratory judgment while timely paying royalties and remaining faithful to the license agreement in all other respects. Id. at 1380.

In holding that [HN5] there was no actual case or controversy for purposes of the Declaratory Judgment Act, we determined that the license, "unless materially breached, obliterated any reasonable apprehension of a lawsuit," and that once the licensor and [*8] licensee "formed the license, an enforceable covenant not to sue, the events that led to the formation [of the license] became irrelevant." Id. at 1381.

We agree with the district court that Gen-Probe is determinative of this case. Any controversy that may have existed between MedImmune and Centocor prior to and during their various negotiations vanished when MedImmune executed the license agreement, which is a covenant by Centocor not to sue. Quite simply, once the license agreement was in place and MedImmune was in compliance with the terms of the agreement, MedImmune could not be under a reasonable apprehension that it would face an infringement suit by Centocor. n1

---------- Footnotes ----------

n1 MedImmune argues that the license agreement contemplated that it could institute a declaratory judgment action of invalidity and/or unenforceability with respect to the '715 patent. This is so, MedImmune asserts, because "the sublicense agreement contained ... no agreement not to litigate." (Br. of Appellant at 22.) This assertion overlooks the fact that a license is, by its nature, an agreement not to litigate. A licensor agrees to receive royalties or other consideration from the licensee in exchange for a covenant not to sue or disturb the licensee's activities.

---------- End Footnotes ----------

[*9]

III.

MedImmune does not seriously dispute that Gen-Probe is virtually on "all fours" with this case. Rather, it contends that we should not follow Gen-Probe. MedImmune argues that Gen-Probe is inconsistent with Supreme Court precedent and with prior Federal Circuit precedent. Consequently, it urges that, as a panel, we are not obligated to follow it. See Atl. Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 839 2n. (Fed. Cir. 1992) (positing that [HN6] "[a] decision that fails to consider Supreme Court precedent does not control if the court determines that the prior panel would have reached a different conclusion if it had considered controlling precedent"); Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir. 1988) ("Where there is direct conflict" between two Federal Circuit panel decisions, "the precedential decision is the first."). We do not agree with MedImmune that Gen-Probe is inconsistent with controlling Supreme Court and Federal Circuit authority.

First, MedImmune argues that Gen-Probe is fatally flawed because it failed to recognize the decision of the Supreme Court in Cardinal Chemical Co. v. Morton International, 508 U.S. 83, 124 L. Ed. 2d 1, 113 S. Ct. 1967 (1993). [*10] We think, however, that Gen-Probe's failure to mention Cardinal Chemical reflects the fact that Cardinal Chemical was inapposite to Gen-Probe, rather than oversight on the part of the Gen-Probe court. The Supreme Court stated in Cardinal Chemical that its decision did not concern the jurisdiction of federal district courts:

Under its current practice, the Federal Circuit uniformly declares that the issue of patent validity is "moot" if it affirms the District Court's finding of noninfringement and if, as in the usual case, the dispute between the parties does not extend beyond the patentee's particular claim of infringement. That practice, and the issue before us, therefore concern the jurisdiction of an intermediate appellate court -- not the jurisdiction of either a trial court or this Court.

Id. at 95 (emphasis added). Consistent with the Court's statement of the limited issue before it in Cardinal Chemical, [HN7] we have twice rejected the idea that Cardinal Chemical was meant to alter how a federal trial court determines whether a case or controversy exists over a declaratory judgment suit. See Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995) [*11] (Cardinal Chemical "does not revolutionize the justiciability of declaratory judgment actions attacking a patent's validity ... and nothing in Cardinal undermines our decisions on declaratory justiciability at the trial court level."); Lamb-Weston, Inc. v. McCain Foods, Ltd., 78 F.3d 540, 545 (Fed. Cir. 1996) ("The Supreme Court's decision in Cardinal Chemical is limited to the specific facts of that case.").

MedImmune also argues that Gen-Probe is inconsistent with the Supreme Court's rejection of the doctrine of licensee estoppel in Lear, Inc. v. Adkins, 395 U.S. 653, 23 L. Ed. 2d 610, 89 S. Ct. 1902 (1969). This argument was addressed and rejected in Gen-Probe, 359 F.3d at 1381, and we likewise reject it here. [HN8] Although Lear held that a licensee is not estopped from challenging the validity of a licensed patent, 395 U.S. at 670-71, "Lear ... left unresolved the question when a federal court has jurisdiction of a licensee's claim of patent invalidity." C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 878 (Fed. Cir. 1983). In other words, the fact that a party is not estopped from making an argument [*12] does not mean that federal courts have jurisdiction to entertain that argument in all circumstances.

Second, MedImmune urges that Gen-Probe is at odds with three decisions of this court: C.R. Bard, Cordis Corp. v. Medtronic, Inc., 780 F.2d 991 (Fed. Cir. 1985), and Intermedics Infusaid, Inc. v. Regents of the University of Minnesota, 804 F.2d 129, 133 (Fed. Cir. 1986). We do not agree.

C.R. Bard noted that complete termination of the license may not be required for a licensee to sustain a declaratory judgment suit. 716 F.2d at 880. It does not follow from that proposition, however, that all licensees in good standing can challenge the validity of the licensed patent at their discretion, without regard to whether an actual controversy exists with the licensor.

Specifically, in determining that there was a case or controversy supporting jurisdiction over a licensee's declaratory judgment suit for, among other things, invalidity of the licensed patent, the C.R. Bard court found two facts to be important. First, the licensee had ceased paying royalties. Although this fact did not itself terminate the license, it constituted [*13] "a material breach of the agreement that, under the very terms of the agreement, enabled [the licensor] to terminate the agreement." Id. at 881. Second, the licensor had shown a willingness to enforce its rights by filing a state court action to recover the royalty payments. Id. at 881. This court then applied the "reasonable apprehension" test to these facts, determining that the licensee had a reasonable apprehension of suit. Id.

By contrast, in this case MedImmune can have no reasonable apprehension of suit -- indeed, it can have no apprehension of suit at all -- because there is nothing for which Centocor can sue MedImmune. It is undisputed that MedImmune continues to pay timely royalties for Synagis (R) and is not otherwise in breach of the agreement. The fact that Centocor did sue MedImmune, after MedImmune filed its declaratory judgment suit, does not alter the analysis. [HN9] The presence or absence of a case or controversy is based on facts at the time the complaint was filed. See, e.g., GAF Bldg. Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 483 (Fed. Cir. 1996) ("Later events may not create jurisdiction where [*14] none existed at the time of filing. Rather, the presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed." (citations omitted)).

MedImmune's reliance on Cordis also is misplaced. Cordis did not address the question of whether there is a case or controversy sufficient to support subject matter jurisdiction over a licensee's suit for a declaratory judgment of patent invalidity where the licensee is not in breach of the license agreement. See generally 780 F.2d at 993-95. In Cordis, the licensee sought a declaration that the licensed patent was invalid. Id. at 993. However, the licensee also sought to pay royalties into escrow pendente lite, and to enjoin the licensor from canceling the license agreement. Id. It was these latter two requests, granted by the district court, that were before this court on appeal. See id. n2

---------- Footnotes ----------

n2 These issues were before the court based upon 28 U.S.C. §§ 1292(a) & (c), which confer jurisdiction upon this court to hear appeals from orders granting injunctions.

---------- End Footnotes ----------

MedImmune points to [*15] Intermedics for the proposition that when a licensee wishes to maintain its license, it must continue to pay royalties to the licensor. See 804 F.2d 129, 133 (citing Cordis). That proposition, however, does not explain how there could be a case or controversy where, as here, the licensee is fully paying royalties directly to the licensor and is maintaining the license.

IV.

Finally, MedImmune urges us – assuming we conclude that we are bound by Gen–Probe – to recommend to the full court that it act en banc to overrule that decision. [HN10] Although a three–judge panel of this court may not overrule a precedential decision of a previous panel, see, e.g., Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1366 (Fed. Cir. 2002), it may recommend en banc review of the decision. See Federal Circuit Rule 35(a) 2)((2004). We decline to do that in this case. Most importantly, as we have just explained, Gen–Probe is consistent with both Supreme Court precedent and with prior precedent of this court.

Beyond that, we reject MedImmune's argument that Gen–Probe should be overruled because it creates a "Hobson's choice. **[*16]** " Specifically, MedImmune argues that it must "choose between paying tribute to a suspect patent and tying its fate to the uncertainty of patent litigation," with all of the attendant risks of such litigation. (Reply Br. of Appellant, at 2.) MedImmune's argument proves too much. Every potential infringer who is threatened with suit, or who is sued, for patent infringement must decide whether to settle or fight. In short, the "Hobson's choice" about which MedImmune complains arises not from Gen–Probe, but from Article III's requirement that, before a district court exercises jurisdiction in a declaratory judgment suit, there must be an actual controversy between the parties. For the reasons set forth above, such a controversy does not exist here.

CONCLUSION

Because the district court did not err in ruling that no Article III case or controversy existed to support MedImmune's declaratory judgment suit, it properly dismissed the suit for lack of jurisdiction. Therefore, the judgment of the district court is

AFFIRMED.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

MEDIMMUNE, INC.,	
Plaintiff,	
vs.	**Civil Action No. AW-02-1135**
CENTOCOR, INC., et. al.,	
Defendant.	

MEMORANDUM OPINION

Currently pending before the Court are Defendants' Fourth Motion to Dismiss [213] and Motion to Reopen [239]. The motions have been fully briefed by all parties. No hearing is deemed necessary. *See* D. Md. R.105.6. Upon consideration of the arguments made in support of, and in opposition to, the respective motions, the Court makes the following determinations.

I. BACKGROUND

A. Factual Background

The Court takes the facts necessary for adjudication of the pending motion to dismiss from the Amended Complaint. At the heart of this controversy is a patent which purports to cover "methods for producing functional immunoglobin" and relates to the use of genetically altered cells to generate antibody molecules in the laboratory. The inventors ("Applicants") applied to the United States Patent and Trademark Office ("PTO") on August 27, 1984. The PTO issued the Patent ("'715 Patent") fourteen years later in 1998. The '715 Patent has been assigned to the Universities. Prior to the issuance of the Patent on November 10, 1992, Defendant obtained an exclusive license to the Patent through an agreement

with the Universities.[1]

In the years preceding the issuance of the Patent, and prior to Plaintiff's awareness of it, Plaintiff was developing a drug called Synagis® which was approved by the Food and Drug Administration ("FDA") on June 18, 1998. Synagis® is a humanized monoclonal antibody that "targets a particular virus or source of disease." These monoclonal antibodies are artificially synthesized using recombinant DNA technology. Plaintiff began selling Synagis® in September 1998, after which it became one of Plaintiff's most important and successful pediatric drugs.

On May 19, 1999, Defendant contacted Plaintiff to inform it that Synagis® was infringing on the '715 Patent. Plaintiff disagreed that Synagis® infringed on the Patent but was concerned about the allegation. Plaintiff responded to Defendant by claiming that Synagis® did not infringe on the Patent. Defendant then proceeded to contact Abbott Laboratories, a party contracted to do business with Plaintiff for Synagis®, and informed Abbott that the product was an infringement of the Patent. Plaintiff eventually agreed to enter into a Sublicense Agreement with Defendant in which it agreed to pay royalties to Defendant. After the formation of the agreement, Plaintiff claims, *inter alia*, that it came upon information which demonstrated that the Patent was invalid and unenforceable because of, among other reasons, "inequitable conduct" by the Applicants during the patent application process before the PTO.

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[1]In the agreement between Centocor and the Universities, the Universities granted a "world-wide" license to Centocor to make, use and sell Licensed Products (which are defined as any Licensed Patent Products or Licensed Non-Patent Products). The Universities reserved the right to use the Patent for not-for-profit research purposes. They also reserved the right to grant non-exclusive sublicenses to four companies with which they were negotiating such agreements, and they reserved the right to bring legal action against any alleged infringer. Among other rights granted to Centocor in the Agreement was the right upon notice to the universities to sue any alleged infringer, subject to the Universities right to bring suit within three months of the notice. Centocor agreed to seek sublicenses with third parties. Centocor's right to sublicense was subject to this restriction: "Any proposed sublicense shall be subject to the prior written approval of Columbia, which approval shall not be unreasonably withheld." Agreement §§ 2, 3.1, 5.1, 12, 13.4, 13.5(d).

B. Procedural Background

Plaintiff initiated this action on April 5, 2002. On July 1, 2002, Defendant Centocor filed a Motion to Dismiss for Declaratory Judgment, which was denied by this Court in a memorandum opinion and order dated December 12, 2002. In that order, this Court additionally denied a Motion to Transfer that had been filed subsequently to the Motion to Dismiss and directed Plaintiff to join the other two Defendants to this action. On January 6, 2003, Plaintiff filed an amended complaint in compliance with the Court's order.

On May 5, 2003, Defendants moved to dismiss or for judgment on the pleadings. Subsequently, on May 15, 2003, Defendants filed a Cross Motion to Dismiss for lack of jurisdiction. The first of these motions was granted on July 15, 2003, with leave given to Plaintiff to amend the Complaint. The second motion was denied in the same memorandum opinion and order. On July 30, 2003, Plaintiff filed its second Amended Complaint.

Most recently, on March 22, 2004, Defendants filed a fourth Motion to Dismiss for lack of jurisdiction, based on new law issued by the Federal Circuit March 5, 2004. *See Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004)(holding declaratory action not properly before the court where licensing agreement is in place and licensee continues to pay royalties pursuant to contract). On May 20, 2004, this Court entered an order staying the proceedings, based upon the assertion made by Plaintiff that the Federal Circuit had not yet ruled on Gen-Probe's Petition for Rehearing *En Banc*. Five days later, Defendants filed a Motion to Reopen based upon a disposition sheet from the Federal Circuit indicating that the appellate court denied Gen-Probe's petition May 24, 2004.

II. **DISCUSSION**

A. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), a court should not dismiss a complaint "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46. The Fourth Circuit has stated,

> [A] Rule 12(b)(6) motion should only be granted if, after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief.

Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir.1999). When considering a motion under Fed. R. Civ. P. 12(b)(1), the Court must first determine which way the motion has been presented. If it is contended that the Plaintiff has failed to allege sufficient facts upon which to based subject matter jurisdiction, then the Plaintiff is afforded all of the same procedural protections as are available under the Rule 12(b)(6) standard. *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982).

B. Analysis

1. *Motion to Reopen*

For the very reasons cited by Defendants, the Court finds Plaintiff's argument stemming from Gen-Probe's attempt to bring its appeal before the Supreme Court unpersuasive. The Supreme Court does not have time to hear but a small percentage of the cases with parties seeking to present arguments before it. In any event, unless and until the decision is overturned by the Supreme Court, the Federal Circuit's opinion is controlling law over the matter presently before this Court. Accordingly, the Court will address the issues presented in the Fourth Motion to Dismiss. However, in light of the decision reached with respect to that motion, the Court will not reopen the case, but simply issue its decision, keeping the case closed.

2. *Fourth Motion to Dismiss*

In *Gen-Probe*, the Federal Circuit analyzed in depth the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a). The Court then, faced with facts identical in all material aspects to the instant case, found that a complainant fails to meet that requirement when it chooses to enter into an agreement to pay royalties to the owner of a patent and then abides by the terms of that contract. The appellate court launched into a discussion of a case cited prominently by Plaintiff,*Lear, Inc. v. Adkins*, 395 U.S. 653 (1969)(finding that the licensee is not barred from challenging a patent's validity based upon that license alone). Citing *Studiengesellschaft Kohle m.b.H. v. Shell Oil, Co.*, 112 F.3d 1561 (Fed. Cir. 1997), the Court found the following:

> While that case did not discuss jurisdiction under the Declaratory Judgment Act, this court stated: [A] licensee ... cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid. *Shell Oil*, 112 F.3d at 1568. This language posits that a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent.

Gen-Probe, 359 F.3d at 1381.

This Court not only finds the conclusions of the Federal Circuit compelling, but, unlike the arguments put forth by Plaintiff, this Court finds them controlling as well. Plaintiff maintains that subject matter jurisdiction is not a substantive issue, but instead a procedural one and thus, Fourth Circuit law should prevail. In support of this contention, Plaintiff cites *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999). However, in that same opinion, on that same page, the Federal Circuit stated as one of the questions to which Federal Circuit law applies, "whether there is a sufficient controversy between the parties to permit an accused infringer to bring an action seeking a declaratory judgment of patent infringement or invalidity." *Id.* (citing *Goodyear Tire & Rubber Co. v. Releasomers*,

Inc., 824 F.2d 953, 954-55 (Fed. Cir. 1987). Since the Court finds that *Gen-Probe* is controlling over the matter currently before it, the Court will not reach the broader arguments raised by Plaintiff addressing its belief that the decision was wrongly decided.

III. CONCLUSION

For the reasons stated above, the Court will DENY Defendants' Motion to Reopen, but will GRANT Defendants' Fourth Motion to Dismiss. An Order consistent with this Opinion will follow.

June 17, 2004
Date

/s/
Alexander Williams, Jr.
United States District Judge

TORPHARM, INC., APOTEX CORP. and APOTEX, INC., Plaintiffs, v. PFIZER INC. and WARNER LAMBERT COMPANY (n/k/a WARNER-LAMBERT LLC), Defendants.

Civ. No. 03-990-SLR

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2004 U.S. Dist. LEXIS 11930

June 28, 2004, Decided

SUBSEQUENT HISTORY: Vacated by, Remanded by Apotex Inc. v. Pfizer Inc., 2005 U.S. App. LEXIS 5930 (Fed. Cir., Apr. 11, 2005)

DISPOSITION-1: [*1] Defendants' motions to dismiss granted.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant inventor corporation filed a motion to dismiss a declaratory judgment action brought by plaintiff generic manufacturer. The manufacturer sought a declaration that its generic version of the inventor's patented drug would not infringe the patent.

OVERVIEW: The manufacturer sought a declaration that its generic version of the inventor's patented drug would not infringe the inventor's patent. The inventor filed a motion to dismiss the complaint for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1). The inventor argued that the manufacturer had not established that a case or controversy existed. The court used a two-part test, looking first at whether the inventor had taken action to create a reasonable apprehension on the part of the manufacturer that it would face an infringement suit, and second at whether the manufacturer was taking action which would constitute infringement. The court held that the inventor did not engage in conduct sufficient to give the manufacturer reasonable apprehension of suit at the time the complaint was filed. The only contact between the parties was initiated by the manufacturer. The inventor's statement that it would enforce its patent did not create a reasonable apprehension of suit, nor did the inventor's actions against infringers of other types of patented drugs. Because there was no justiciable case or controversy, the court did not have subject matter jurisdiction.

OUTCOME: The court granted the inventor's motion to dismiss.

CORE TERMS: patent, generic, apprehension, infringement, holder, brand, hydrochloride, certification, quinapril, declaratory judgment, subject matter jurisdiction, Medicare Act, declaratory judgment action, forty-five, invalid, filer, prong, patent infringement, exclusivity, generic drug, innovator, infringe, manufacture, act of infringement, actual controversy, infringed, two-part, notice, marketing, conferees

LexisNexis(TM) Headnotes

Patent Law > Claims & Specifications > Enablement Requirement > General Overview

Patent Law > Subject Matter > Products > Manufactures

Patent Law > Infringement Actions > General Overview

[HN1]Under the Federal Food, Drug, and Cosmetic Act, an innovator pharmaceutical company who seeks to manufacture a new brand drug is required to file a new drug application (NDA) with the Federal Food and Drug Administration (FDA). 21 U.S.C.S. § 355(a). Submitting an NDA is frequently a time-intensive and costly process because, among other things, the NDA must contain detailed clinical studies of the brand drug's safety and efficacy. The NDA also must include a list of patents which claim the brand drug. If the FDA approves an NDA, then it publishes, or "lists," information about the brand drug and patents covering the brand drug's approved aspects in a publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book."

Patent Law > Ownership > Conveyances > Licenses

Patent Law > Infringement Actions > Defenses > Experimental Use & Testing

[HN2]See 21 U.S.C.S. § 355(b)(1).

Patent Law > Infringement Actions > Infringing Acts > Make

[HN3]A generic does not commit an act of infringement in submitting an abbreviated new drug application. 35 U.S.C.S. § 271(e)(1).

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN4]With a paragraph I or II certification, the Food and Drug Administration (FDA) may grant approval as soon as it is satisfied that the product is safe and effective. 21 U.S.C.S. § 355(j)(5)(B)(i). Under a paragraph III certification, the FDA may approve the abbreviated new drug application as soon as the patent on the brand drug expires. 21 U.S.C.S. 355(j)(5)(B)(ii). If the generic enters paragraph III certifications for more than one patent, then the FDA may not grant approval until the last patent expires.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview

Patent Law > Remedies > Declaratory Relief

Patent Law > Infringement Actions > Defenses > Experimental Use & Testing

[HN5]Filing an abbreviated new drug application (ANDA) with a paragraph IV certification presents a more unique situation; it is considered to be a "technical" or "artificial" act of infringement. 21 U.S.C.S. § 271(e)(2)(A). Consequently, the ANDA applicant must explain why a generic version of the previously approved brand drug would not infringe the patent covering the previously approved brand drug or why such patent is invalid. 21 U.S.C.S. § 355 (j)(2)(B)(i). In response, the patent holder has the option of filing a patent infringement action within 45 days after receiving such notice. 21 U.S.C.S. § 355(j)(5)(B)(iii). During this window, the generic may not file a declaratory judgment action based upon the filing of the ANDA. If the patent holder fails to bring suit, then the Food and Drug Administration (FDA) may approve the ANDA. However, if the patent holder elects to bring suit, then the effective date of any FDA approval is delayed for either 30 months or until a court rules that the patent is invalid or not infringed, whichever occurs first.

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN6]The first generic to file an abbreviated new drug application (ANDA) containing a paragraph IV certification is known as a "first filer" and is eligible for a 180-day exclusivity period. This means that the first filer is entitled to have the sole generic version of the brand drug on the market for the first 180-days following the earlier of: (1) the date of the first commercial marketing of the generic drug by the first filer; or (2) a court decision of noninfringement or invalidity by any ANDA applicant in any action. 21 U.S.C.S. § 355(j)(5)(B)(iv). Any subsequent ANDA filer must wait until the expiration of this 180-day exclusivity period before the Food and Drug Administration will approve its ANDA. If the first filer does not opt to commercially market its generic drug, then subsequent ANDA filers may trigger the 180-day exclusivity period by obtaining a court decision of noninfringement or invalidity.

Patent Law > Remedies > Declaratory Relief

Civil Procedure > Remedies > Declaratory Relief

Patent Law > Infringement Actions > Defenses > Experimental Use & Testing

[HN7]The Medicare Act amended 21 U.S.C.S. § 355(j)(5)(C)(i)(I)(2) to provide that a generic who has filed a paragraph IV certification may bring a declaratory judgment action against the patent holder and/or holder of a new drug application (NDA) if: (1) the 45 day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the holder of the NDA brought an action for patent infringement within the 45 day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the abbreviated new drug application. The Medicare Act also amended 21 U.S.C.S. § 355(j)(5)(C)(i)(II) to provide that if the above three conditions are satisfied, then the applicant may, in accordance with 28 U.S.C.S. § 2201, bring a civil action under such section against the patent owner or holder of the NDA for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

Patent Law > Infringement Actions > Infringing Acts > Make

Patent Law > Jurisdiction & Review > General Overview

Civil Procedure > Remedies > Declaratory Relief

[HN8]The Medicare Act added a new provision to 35 U.S.C.S. § 271(e), the section of the patent code relevant to infringement actions. This provision provides that if: (1) a generic makes a paragraph IV certification; and (2) the patent holder or holder of a new drug application fails to sue the generic for patent infringement within the 45 day window after receiving notice; then (3) the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under 28 U.S.C.S. § 2201 for a declaratory judgment that such patent is invalid or not infringed. 35 U.S.C.S. § 271(e)(5).

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Jurisdiction Over Action

[HN9]Federal courts are courts of limited jurisdiction. They possess only that power authorized by the Constitution and statute. It is to be presumed that a cause lies outside this limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction. A subject matter jurisdiction attack under Fed. R. Civ. P. 12(b)(1), therefore, challenges the court's jurisdiction to address the merits of the complaint. A party may raise the lack of subject matter jurisdiction at any time; it cannot be waived. Fed. R. Civ. P. 12(h)(3). In fact, the court is obliged to address the issue on its own motion, if not raised by the parties. Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Jurisdiction Over Action

[HN10]Under Fed. R. Civ. P. 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). Under a facial challenge, the court must accept as true the allegations contained in the complaint. Dismissal for a facial challenge to jurisdiction is proper only when the claim clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or is wholly insubstantial and frivolous. Under a factual attack, however, the court is not confined to allegations in the complaint, but may consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction. No presumptive truthfulness attaches to the plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.

Civil Procedure > Remedies > Declaratory Relief

[HN11]See 28 U.S.C.S. § 2201(a).

Civil Procedure > Justiciability > Case or Controversy

Civil Procedure > Remedies > Declaratory Relief

[HN12]Under the Declaratory Judgment Act, 28 U.S.C.S. § 2201, a court may declare the rights and other legal relations of any interested party only where there exists an "actual controversy." This requirement effectuates U.S. Const. art. III, which authorizes the federal judiciary to hear justiciable cases and controversies.

Patent Law > Inequitable Conduct > General Overview

Civil Procedure > Justiciability > Case or Controversy

Patent Law > Infringement Actions > General Overview

[HN13]To guide the case-or-controversy analysis in patent-based declaratory judgment suits, there is a two-part test. For actual controversy to exist, there must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity. The burden is on the declaratory judgment plaintiff to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed. Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction.

Patent Law > Remedies > Declaratory Relief

Civil Procedure > Justiciability > Case or Controversy

Civil Procedure > Remedies > Declaratory Relief

[HN14]The first prong of the test to determine whether a justiciable controversy exists in a declaratory judgment action regarding potential patent infringement looks to the patent holder's conduct. If a defendant expressly charges that a plaintiff's current activity constitutes infringement, then there is an actual controversy. In light of the subtleties in lawyer language, however, courts have not required an express infringement charge. When the defendant's conduct, including its statements, falls short of an express charge, the court must consider the "totality of the circumstances" in determining whether the defendant's conduct meets the first prong of the test. Thus, the declaratory judgment plaintiff must demonstrate conduct that rises to a level sufficient to indicate an intent of the patent holder to enforce its patent, i.e., to initiate an infringement action. Subjective impressions of the declaratory judgment plaintiff, however, are insufficient to satisfy the requirement. The court must find objective facts considering the totality of the circumstances at the time the complaint was filed.

Civil Procedure > Justiciability > Case or Controversy

Patent Law > Jurisdiction & Review > General Overview

Civil Procedure > Remedies > Declaratory Relief

[HN15]The second prong of the test to determine whether a justiciable controversy exists in a declaratory judgment action regarding potential patent

infringement looks to the potential infringer's conduct. The potential infringer must be engaged in an actual making, selling, or using activity subject to an infringement charge or must have made meaningful preparation for such activity. This prong insures that the declaratory judgment plaintiff has a "true interest to be protected" and prevents such plaintiff from seeking an advisory opinion on potential liability for initiating some future activity.

Patent Law > Remedies > Declaratory Relief

Civil Procedure > Justiciability > Case or Controversy

Civil Procedure > Remedies > Declaratory Relief

[HN16]The plain language of 21 U.S.C.S. § 355(j)(5)(C)(i)(II) requires a generic to satisfy three prerequisites before lodging a declaratory judgment action against a patent holder; this provision does not in any way address subject matter jurisdiction. The plain language of 35 U.S.C.S. § 271(e)(5), on the other hand, reaches the issue of subject matter jurisdiction. It requires courts to exercise subject matter jurisdiction in a patent-related declaratory judgment action consistent with the Constitution. A generic must satisfy the case and controversy requirement set forth in U.S. Const. art. III.

Civil Procedure > Remedies > Declaratory Relief

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN17]The Medicare Act, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, (2003), applies to all proceedings pending on or after December 8, 2003.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview

Civil Procedure > Remedies > Declaratory Relief

Patent Law > Remedies > Declaratory Relief

[HN18]The Medicare Act, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, (2003), states that a declaratory judgment action may not be brought unless: (1) the 45 day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor holder of the new drug application (NDA) brought an action for infringement of the patent within the 45 day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the abbreviated new drug application (ANDA). The 45 day window, therefore, relates to notice of the ANDA filing containing the paragraph IV certification, not notice of the complaint.

Civil Procedure > Justiciability > Case or Controversy

Patent Law > Infringement Actions > Defenses > Experimental Use & Testing

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN19]The act of listing a patent in the "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book," does not create an "actual controversy"; and does not give potential infringers reason to fear suit.

Civil Procedure > Justiciability > Case or Controversy

Civil Procedure > Remedies > Declaratory Relief

Patent Law > Remedies > Declaratory Relief

[HN20]The test for finding a "controversy" for jurisdictional purposes is a pragmatic one and cannot turn on whether the parties use polite terms in dealing with one another or engage in more bellicose saber rattling. The need to look to substance rather than form is especially important in this area, because in many instances the parties are sensitive to the prospect of a declaratory judgment action and couch their exchanges in terms designed either to create or defeat declaratory judgment jurisdiction. In the end, the question is whether the relationship between the parties can be considered a "controversy," and that inquiry does not turn on whether the parties have used particular "magic words" in communicating with one another. No apprehension of suit exists where the patent holder has made no contact with the declaratory judgment plaintiff.

Civil Procedure > Justiciability > Case or Controversy

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN21]A patent holder's statement that it intends to enforce its patent does not create a reasonable apprehension of suit.

COUNSEL: Steven J. Balick, Esquire, John G. Day, Esquire, Ashby & Geddes, Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: William A. Rakoczy, Esquire, Paul J. Molino, Esquire, Deanne M. Mazzochi, Esquire, Matthew O. Brady, Esquire, Lord Bissell & Brook LLP, Chicago, Illinois.

Jack B. Blumenfeld, Esquire, James W. Parrett, Esquire, Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Dimitrios T. Drivas, Esquire, Jeffrey J.

Oelke, Esquire, Adam Gahtan, Esquire, Brendan G. Woodard, Esquire, White & Case LLP, New York, New York.

JUDGES: Sue L. Robinson, United States District Judge.

OPINIONBY: Sue L. Robinson

OPINION: MEMORANDUM OPINION

Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On October 29, 2003, plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. filed a declaratory judgment action against defendants Pfizer Inc. and Warner-Lambert Company. Plaintiffs seek a declaration that their generic version of Pfizer's patented drug Accupril(R) will not infringe U.S. Patent No. 4,743,450 ("the '450 patent"). (D.I. 1) On February 23, 2004, plaintiffs filed an **[*2]** amended complaint to provide additional information about the statutory scheme for the approval of generic drugs. (D.I. 18)

Plaintiff TorPharm is incorporated under the laws of Canada with its principal place of business in Etobicoke, Ontario, Canada. (D.I. 1 at P 5) TorPharm develops, manufactures, and markets generic drugs, in particular solid oral dosage forms, such as capsules and tablets, for sale and use in the United States. (Id.) Plaintiff Apotex Corp. is incorporated under the laws of the State of Delaware with its principal place of business in Lincolnshire, Illinois. (D.I. 1 at P 6) Apotex is the United States marketing and sales affiliate for TorPharm. (Id.) Plaintiff Apotex, Inc. is incorporated under the laws of Canada with its principal place of business in Weston, Ontario, Canada. (Id. at P 7) Defendant Pfizer Inc. is organized under the laws of the State of Delaware with its principal place of business in New York, New York. (Id. at P 9) Defendant Warner-Lambert LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in Morris Plains, New Jersey. n1 (D.I. 1 at P 10)

---------- Footnotes ----------

n1 As of June 19, 2000, Warner-Lambert Company became a wholly owned subsidiary of defendant Pfizer Inc.. Warner-Lambert Company subsequently became Warner-Lambert LLC. (Id. at P 10)

---------- End Footnotes----------

[*3]

On January 8, 2004 and April 1, 2004, defendants filed motions to dismiss the complaint and the amended complaint, respectively, for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1). (D.I. 8, 20) These motions are presently before the court. For the reasons to follow, the court grants both motions.

II. BACKGROUND

A. Regulatory Approval for Brand Drugs

[HN1]Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), an innovator pharmaceutical company ("innovator") who seeks to manufacture a new brand drug is required to file a new drug application ("NDA") with the Federal Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Submitting an NDA is frequently a time-intensive and costly process because, among other things, the NDA must contain detailed clinical studies of the brand drug's safety and efficacy. The NDA also must include a list of patents which claim the brand drug:

[HN2]The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such **[*4]** drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug... . Upon approval of the application, the Secretary shall publish information submitted under [this section].

21 U.S.C. § 355(b)(1). If the FDA approves an NDA, then it publishes, or "lists," information about the brand drug and patents covering the brand drug's approved aspects in a publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Id.

B. Regulatory Approval for Generic Drugs

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282, n2 a generic drug manufacturer ("generic") who seeks approval to market

a generic version of a previously approved brand drug may submit an abbreviated new drug application ("ANDA") to the FDA. n3 21 U.S.C. § 355(j). In the ANDA, a generic may rely on the safety and efficacy [*5] studies previously submitted to the FDA in the innovator's NDA by showing the generic drug's bioequivalence with the previously approved brand drug. 21 U.S.C. § 355(j)(2)(A). The generic also must "certify" whether the generic drug would infringe the patent(s) listed in the Orange Book for the brand drug. 21 U.S.C. § 355(j) (2) (A) (vii). To satisfy this requirement, a generic may make one of four possible certifications for each patent claiming either the listed brand drug or the use of the listed brand drug: (I) that no patent information on the brand drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a stated date; or (IV) that the listed patent is invalid or will not be infringed by the generic product. 21 U.S.C. § 355(j) (2) (A) (vii) (I)-(IV). These options are designated as paragraph I, II, III, and IV certifications, respectively.

---------- Footnotes ----------

n2 The Drug Price Competition and Patent Term Restoration Act of 1984 is more commonly known as the "Hatch-Waxman Act." It amended various provisions of the FFDCA and Title 35 of the United States Code relating to patents. Title 1 of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citing H.R. Rep. No. 98-857, pt. 1 at 14 (1984)).

[*6]

n3 [HN3]A generic does not commit an act of infringement in submitting an ANDA. 35 U.S.C. § 271 (e)(1)("It shall not be an act of infringement to make, use, offer to sell, or sell ... a patented invention ... solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.").

---------- End Footnotes----------

[HN4]With a paragraph I or II certification, the FDA may grant approval as soon as it is satisfied that the product is safe and effective. 21 U.S.C. § 355(j) (5) (B) (i). Under a paragraph III certification, the FDA may approve the ANDA as soon as the patent on the brand drug expires. 21 U.S.C. 355(j)(5)(B)(ii). If the generic enters paragraph III certifications for more than one patent, then the FDA may not grant approval until the last patent expires. [HN5]Filing an ANDA with a paragraph IV certification presents a more unique situation; it is considered to be a "technical" or "artificial" act of infringement. 35 U.S.C. § 271(e)(2)(A)("It shall be an [*7] act of infringement to submit an application under section 505(j) of the [FFDCA] or described in section 505(b) (2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent."); see Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678, 110 L. Ed. 2d 605, 110 S. Ct. 2683 (1990)("An act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271 (e) (2) - the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent."). Consequently, the ANDA applicant must explain why a generic version of the previously approved brand drug would not infringe the patent covering the previously approved brand drug or why such patent is invalid. 21 U.S.C. § 355 (j) (2) (B) (i). In response, the patent holder has the option of filing a patent infringement action within forty-five days after receiving such notice. 21 U.S.C. § 355(j) [*8] (5) (B) (iii). During this window, the generic may not file a declaratory judgment action based upon the filing of the ANDA. Id. If the patent holder fails to bring suit, then the FDA may approve the ANDA. Id. However, if the patent holder elects to bring suit, then the effective date of any FDA approval is delayed for either thirty months or until a court rules that the patent is invalid or not infringed, whichever occurs first. Id.

[HN6]The first generic to file an ANDA containing a paragraph IV certification is known as a "first filer" and is eligible for a 180-day exclusivity period. This means that the first filer is entitled to have the sole generic version of the brand drug on the market for the first 180-days following the earlier of: (1) the date of the first commercial marketing of the generic drug by the first filer; or (2) a court decision of noninfringement or invalidity by any ANDA applicant in any action. 21 U.S.C. § 355(j) (5) (B) (iv). Any subsequent ANDA filer must wait until the expiration of this 180-day exclusivity period before the FDA will approve its ANDA. n4

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N4 If the first filer does not opt to commercially market its generic drug, then subsequent ANDA filers may trigger the 180-day exclusivity period by obtaining a court decision of noninfringement or invalidity.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

[*9]

B. The Medicare Act

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60 (the "Medicare Act"). (D.I. 18 at P 48) Title XI of the Act, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA. (Id.) [HN7]In particular, the Medicare Act amended 21 U.S.C. § 355(j) (5) (C) (i) (I) (2) to provide that a generic who has filed a paragraph IV certification may bring a declaratory judgment action against the patent holder and/or holder of the NDA if: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the holder of the NDA brought an action for patent infringement within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The Medicare Act also amended 21 U.S.C. § 355(j)(5)(C)(i)(II) to provide that if the above three conditions are satisfied, then

the applicant ... may, in accordance with section 2201 of title 28, United States [*10] Code, bring a civil action under such section against the [patent] owner or holder [of the NDA] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

[HN8]The Medicare Act likewise added a new provision to 35 U.S.C. § 271(e), the section of the patent code relevant to infringement actions. This provision provides that if: (1) a generic makes a paragraph IV certification; and (2) the patent holder or holder of the NDA fails to sue the generic for patent infringement within the forty-five day window after receiving notice; then (3) "the courts of the United States shall, **to the extent consistent with the Constitution,** have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271 (e) (5) (emphasis added).

C. The Brand Drug Product

Accupril(R) is the brand name for *quinapril hydrochloride.* The FDA has approved Accupril(R) for the treatment of hypertension and for the management of heart failure. (D.I. 21 at P 4) Accupril(R) [*11] has been on the market in the United States since 1991. (Id.) In accordance with 21 U.S.C. § 355(b) (1), Pfizer listed the numbers and the expiration dates for the patents covering either Accupril(R) tablets or a method of using those tables with the FDA. (Id.) The FDA, in turn, published this information in the Orange Book. (Id.) The '450 patent is one of the patents found in the Orange Book; it expires on February 24, 2007. (Id.)

D. The First Filer

At a date prior to January 15, 1999, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with paragraph IV certification directed to *quinapril hydrochloride.* (D.I. 22 at P 2) Teva asserted that the '450 patent is invalid. n5 On January 15, 1999, Teva notified defendant Warner-Lambert of this filing. (Id.) Within forty-five days thereafter, defendant Warner-Lambert filed an action against Teva for infringement of the '450 patent in the United States District Court for the District of New Jersey. (Id. at P 4; D.I. 26 at 11) On October 2, 2003, the District of New Jersey held that Teva infringes the '450 patent and granted summary judgment in favor of Pfizer on this ground. See [*12] Warner-Lambert Co. v. Teva Pharms. USA, 289 F. Supp. 2d 515, 545 (D. N.J. 2003). n6 The parties have yet to litigate the issues of validity and enforceability. (D.I. 22 at P 5)

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n5 The FDA approved Teva's ANDA on May 30, 2003. (D.I. 21 at 7)

n6 After receiving this favorable decision, defendants issued a press release commenting on the ruling. Defendants' senior vice president and general counsel stated: "[Defendants] [are] pleased with the court's summary judgment decision because it affirms positions the company has maintained with respect to the Accupril(R) patent from the very beginning of the litigation ... [Defendants] will continue aggressively to defend challenges to its intellectual property." (D.I. 21, ex. D)

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As the first filer, Teva is entitled to a 180-day period of generic exclusivity from the earlier of: (1) the date it first commercially markets generic *quinapril hydrochloride;* or (2) the date of a court decision declaring the '450 patent invalid. See 21 U.S.C. § 355 [*13] (j)(5)(B)(iv)(I), (II). To date, neither event has occurred. If Teva prevails in its litigation against Warner-Lambert and the District of New Jersey declares the '450 patent invalid, then the clock will start running on Teva's 180-day exclusivity period. Other generics who receive FDA approval will be able to begin marketing their generic versions of *quinapril hydrochloride* upon expiration of Teva's period of exclusivity.

E. Plaintiffs' ANDA

On September 13, 2001, plaintiffs filed an ANDA seeking approval to market its own generic version of *quinapril hydrochloride.* (D.I. 18 at P 62) Plaintiffs entered a paragraph IV certification with respect to the '450 patent. (Id. at P 64) Around November 15, 2001, plaintiffs notified defendants about the ANDA filing and the paragraph IV certification pursuant to 21 U.S.C. 355(j)(2)(B)(iv). (Id. at P 67) Defendants did not file a patent infringement action asserting the '450 patent against plaintiffs within forty-five days of receiving this notice. (D.I. 22 at P 6) On February 3, 2004, plaintiffs sent a letter to defendants offering confidential access to their ANDA. (D.I. 18 at P 69; D.I. 21, ex. [*14] G)

F. Other ANDAs Directed to *Quinapril Hydrochloride*

Besides Teva and the plaintiffs at bar, eight other generics have filed ANDAs seeking approval to market generic *quinapril hydrochloride* between January 2001 and May 2003. n7 These generics include: (1) Geneva Pharmaceuticals, Inc; (2) Andrx Pharmaceuticals, Inc.; (3) Par Pharmaceuticals, Inc.; (4) Ivax Pharmaceuticals, Inc.; (5) Mutual Pharmaceutical Company, Inc.; (6) Ranbaxy Pharmaceuticals Inc.; (7) Amide Pharmaceutical, Inc.; and (8) Mylan Pharmaceuticals Inc.. (D.I. 22 at P 7) Pfizer has not initiated litigation against any of these eight companies in connection with their ANDAs. (Id.)

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n7 Though not specifically stated by the parties, the court presumes that each of these generics included paragraph IV certifications in their ANDA filings based upon the parties' representations about these filings.

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III. STANDARD OF REVIEW

[HN9]"Federal courts are courts of limited jurisdiction. They possess only that power authorized by the [*15] Constitution and statute ... It is to be presumed that a cause lies outside this limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction." Kokkonen v. Guardian Life Ins. Co. Of Am., 511 U.S. 375, 377, 128 L. Ed. 2d 391, 114 S. Ct. 1673 (1994)(citations omitted). A subject matter jurisdiction attack under Fed. R. Civ. Pro. 12(b)(1), therefore, challenges the court's jurisdiction to address the merits of the complaint. See Lieberman v. Delaware, 2001 U.S. Dist. LEXIS 13624, 2001 WL 1000936, at *1 (D. Del. 2001). A party may raise the lack of subject matter jurisdiction at any time; it cannot be waived. Fed. R. Civ. P. 12(h)(3). In fact, the court is obliged to address the issue on its own motion, if not raised by the parties. See Neiderhiser v. Berwick, 840 F.2d 213, 216 (3d Cir. 1988). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc., 227 F.3d 62, 69 (3d Cir. 2000).

[HN10]Under Rule 12(b)(1), the court's [*16] jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). Mortensen v. First Fed. Sav. & Loan, 549 F.2d 884, 891 (3d Cir. 1977). Under a facial challenge, the court must accept as true the allegations contained in the complaint. See 2 James W. Moore, Moore's Federal Practice § 12.30 [4] (3d ed. 1997). Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or ... is wholly insubstantial and frivolous.'" Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1408-1409 (3d Cir. 1991) (quoting Bell v. Hood, 327 U.S. 678, 682, 90 L. Ed. 939, 66 S. Ct. 773 (1946)).

Under a factual attack, however, the court is not "confined to allegations in the ... complaint, but [may] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." Gotha v. United States, 36 V.I. 392, 115 F.3d 176, 179 (3d Cir. 1997); see also Mortensen, 549 F.2d at 891-892. "No presumptive truthfulness [*17] attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Carpet Group, 227 F.3d at 69 (quoting Mortensen, 549 F.2d at 891). Because defendants did not answer either

plaintiffs' original complaint or their amended complaint, the court shall treat the instant subject matter jurisdiction challenge as a facial attack.

IV. DISCUSSION

A. The Legal Standard for Declaratory Judgment

The Declaratory Judgment Act states in pertinent part:

> [HN11]In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201(a). [HN12]Under this act, a court may declare the rights and other legal relations of any interested party only where there exists an "actual **[*18]** controversy." Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999). This requirement effectuates Article III of the Constitution, which authorizes the federal judiciary to hear justiciable cases and controversies. n8 See EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996).

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> n8 The Supreme Court has held that Article III is satisfied where there is: (1) an actual or imminent injury-in-fact; (2) that is fairly traceable to the defendant; and (3) is redressible by a favorable decision. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992).
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[HN13]To guide the case-or-controversy analysis in patent-based declaratory judgment suits, the Federal Circuit has developed a two-part test. "For actual controversy to exist, 'there must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and **[*19]** (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" Amana, 172 F.3d at 855 (quoting BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993)). The burden is on the declaratory judgment plaintiff "to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed." Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed. Cir. 1986). "Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." EMC Corp., 89 F.3d at 810.

[HN14]The first prong looks to the patent holder's conduct. BP Chems. Ltd., 4 F.3d at 978. If a defendant expressly charges that a plaintiff's current activity constitutes infringement, then there is an actual controversy. Arrowhead Indus. Water v. Ecolochem, 846 F.2d 731, 736 (Fed. Cir. 1988). In light of the subtleties in lawyer language, however, courts have not **[*20]** required an express infringement charge. Id. (citing Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 956 (Fed. Cir. 1987)). When the defendant's conduct, including its statements, falls short of an express charge, the court must consider the "totality of the circumstances" in determining whether the defendant's conduct meets the first prong of the test. Arrowhead, 846 F.2d at 736. Thus, the declaratory judgment plaintiff must demonstrate "conduct that rises to a level sufficient to indicate an intent [of the patent holder] to enforce its patent, i.e., to initiate an infringement action." EMC Corp., 89 F.3d at 811 (citations omitted). Subjective impressions of the declaratory judgment plaintiff, however, are insufficient to satisfy the requirement. The court must find objective facts considering the totality of the circumstances at the time the complaint was filed. Arrowhead, 846 F.2d at 736.

[HN15]The second prong looks to the potential infringer's conduct. BP Chems. Ltd., 4 F.3d at 978. The potential infringer must be engaged in an actual making, selling, or using activity subject to **[*21]** an infringement charge or must have made meaningful preparation for such activity. This prong insures that the declaratory judgment plaintiff has a "true interest to be protected" and prevents such plaintiff from seeking an advisory opinion on potential liability for initiating some future activity. Arrowhead, 846 F.2d at 736.

B. Defendants' Motion to Dismiss

1. Subject Matter Jurisdiction Pursuant to the Medicare Act

Plaintiffs argue that they are not required to satisfy the reasonable apprehension of suit requirement to confer subject matter jurisdiction pursuant to the amendments

made to 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5) by the Medicare Act. (D.I. 26 at 14) Plaintiffs claim that they need only satisfy the case or controversy requirement of Article III of the Constitution. In this regard, plaintiffs contend that they have been directly injured by defendants because they cannot enter the *quinapril hydrochloride* market with their generic product until after the '450 patent expires due to the "bottleneck" that defendants created by engaging in litigation against Teva. n9 Plaintiffs maintain **[*22]** that a declaratory judgment in their favor will redress this injury as they will be able to market their generic version of *quinapril hydrochloride.* Accordingly, plaintiffs aver that the court has subject matter jurisdiction over the instant dispute.

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n9 Recall that pursuant to 21 U.S.C. 355(j)(5)(B)(iv), the FDA cannot approve plaintiffs' ANDA until 180 days after Teva enters the market with its generic *quinapril hydrochloride* or until a favorable court decision on the '450 patent, whichever is earlier. Plaintiffs claim that Teva will not enter the market because the District of New Jersey found that its generic version of *quinapril hydrochloride* infringed the '450 patent. Plaintiffs also allege that defendants have delayed filing suit against them or any of the other subsequent ANDA filers to avoid triggering a court decision that potentially may find the '450 patent not infringed or invalid.

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The court does not read the plain language of either 21 U.S.C. § 355 **[*23]** (j)(5)(C)(i)(II) or 35 U.S.C. § 271(e)(5) as eliminating the Federal Circuit's two-part test. Rather, [HN16]the plain language of 21 U.S.C. § 355(j)(5)(C)(i)(II) requires a generic to satisfy three prerequisites before lodging a declaratory judgment action against a patent holder; this provision does not in any way address subject matter jurisdiction. The plain language of 35 U.S.C. § 271(e)(5), on the other hand, reaches the issue of subject matter jurisdiction. It requires courts to exercise subject matter jurisdiction in a patent-related declaratory judgment action "consistent with the Constitution." The court interprets this language to mean that a generic must satisfy the case and controversy requirement set forth in Article III. Given that the Federal Circuit established its two-part test to guide the case-or-controversy analysis in conformity with Article III, the court finds that this test is "consistent with the Constitution" and applicable to the litigation at bar.

The court observes that the legislative history for the Medicare Act substantiates this interpretation. Congress specifically contemplated a continuation **[*24]** of the constitutional standard for subject matter jurisdiction, including the reasonable apprehension requirement. According to the House of Representatives conference report,

> the conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effect to delay infringement litigation between generic drug manufacturers and pioneer drug companies. **The conferees expect courts to apply the 'reasonable apprehension' test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.** Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction. The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act. In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought **[*25]** an infringement suit within the [forty-five] days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391, at 836 (2003)(citations omitted)(emphasis added). Taking this explanation together with the Federal Circuit's plain language of the Medicare Act, the court concludes that the two-part test remains as the standard for determining whether a district court has subject matter jurisdiction over a patent-based declaratory judgment action.

Turning to the facts at bar, plaintiffs were not required to comply with the three prerequisites set forth in 21 U.S.C. § 355(j)(5) (C) (i)(II) because they filed their original complaint on October 29, 2003, approximately one month prior to the enactment of the Medicare Act on December 8, 2003. Nevertheless, [HN17]the Medicare Act applies to all proceedings pending on or after December 8, 2003. As such, defendants focus on plaintiffs' amended complaint, which was filed on February 23, 2004, nearly **[*26]** three months after the Medicare Act became effective. To this end, defendants argue that plaintiffs filed their amended

complaint only twenty days after offering defendants confidential access to their ANDA, well within the forty-five day period.

At the outset, the court observes that defendants confuse the prerequisites. [HN18]The Medicare Act states that a declaratory judgment action may not be brought unless: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor holder of the NDA brought an action for infringement of the patent within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The forty-five day window, therefore, relates to notice of the ANDA filing containing the paragraph IV certification, not notice of the complaint or, in the case at bar, the amended complaint. Additionally, compliance with the Medicare Act as of the date of the amended complaint is of no import; the Medicare Act seeks to ensure that a patent holder has full opportunity to consider an ANDA and decide whether to file an infringement action prior **[*27]** to being forced to stand in defense in a declaratory judgment action. This consideration occurs with the filing of an original complaint, not as of the filing of an amended complaint in a suit already in progress. Accordingly, the court declines to dismiss the instant litigation on procedural grounds.

2. Subject Matter Jurisdiction Under the Federal Circuit's Two-Part Test n10

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n10 The parties dispute only the first prong of this test, to wit, whether plaintiffs were in reasonable apprehension of an infringement suit as of October 29, 2003, the date of plaintiffs' original complaint. The court, therefore, confines its analysis to this question. For sake of clarity, the court observes that plaintiffs satisfied the second prong of the two-part test, i.e., activity which could constitute infringement, by filing the ANDA. See 35 U.S.C. § 271(e)(2); see also *infra* Section II, A.

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Plaintiffs argue that they were under a reasonable apprehension of suit at the time they filed their **[*28]** complaint based upon various actions by defendants, including the following: (1) listing the '450 patent in the Orange Book n11 (D.I. 18 at PP 27, 89); (2) failing to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent or to provide plaintiffs with a covenant not to sue (id. at P 89); (3) initiating an infringement lawsuit against Teva regarding the '450 patent (id. at PP 80, 81); (4) stating in a press release "that it will continue to aggressively defend challenges to its intellectual property" (id. at PP 79, 89; D.I. 21, ex. D); and (5) initiating a lawsuit against plaintiffs over a different product (Neurotin(R)), thereby showing a "pattern of aggressively enforcing its patents" against "the generic pharmaceutical industry generally." (Id. at PP 72-78, 89)

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n11 Plaintiffs argue that defendants implied that an infringement action could be brought against any generic who seeks ANDA approval for a generic version of *quinapril hydrochloride* by listing the '450 patent in the Orange Book.

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[*29]

Before delving into the details of plaintiffs' arguments, the court recognizes that it is often difficult to identify whether a reasonable apprehension of suit exists. This question entails a balance, similar to the balance that the Hatch-Waxman Act struck between innovators and generics. On the one hand, a patent owner should not be dragged into court when it has not engaged in threatening or aggressive acts simply because it chooses to inform potential infringers of its patent rights. In the case of the pharmaceutical industry, an innovator has invested a tremendous amount of research effort, dollars, and time into developing and marketing a brand drug. Such innovators also have expended considerable resources in establishing a patent portfolio to protect said brand drug. The court respects both the innovator's efforts and legitimate patent rights and does not easily dismiss these investments. On the other hand, however, the Declaratory Judgment Act was enacted to prevent patent owners from using "guerrilla-like" tactics and attempting "extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with **[*30]** uncertainty and insecurity." Arrowhead, 846 F.2d at 735. As well, the court is mindful that a generic should be entitled to market its generic version of a brand drug if a product does not infringe the patent listed in the Orange Book for the brand drug or said patent is invalid. In such situations, the court appreciates that a declaratory judgment action may be

the only means for a generic to reach the market given the possibility for a so-called "bottleneck."

With this background in mind, the court turns to consider plaintiffs' contentions concerning the first prong of the two-part test. Plaintiffs argue that a generic, in general, is placed in a position of reasonable apprehension of litigation when it submits an ANDA because a patent holder may file a patent infringement action against it. n12 In asserting this position, plaintiffs reference the concurrence from Judge Gajarsa in Minnesota Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775 (Fed. Cir. 2002). Judge Gajarsa opined that

> filing an NDA application meets prong one of the declaratory judgment case or controversy requirement, because filing the application requires the patentee [*31] to maintain that an infringement suit could 'reasonably be asserted' against one who 'engaged in the manufacture, use or sale of the drug.' This is 'conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one.'

Id. at 791 (citations omitted). n13

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n12 Recall that in listing a patent in the Orange Book, a patent holder represents that a claim for infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of the drug. See 21 U.S.C. § 355(b)(1).

n13 Similarly, the D.C. Circuit appears to share this view, stating that
the Federal Circuit has had no occasion to decide whether there is a 'controversy of sufficient immediacy and reality' to support a declaratory judgment action, ... when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.
Mova Pharm. Corp. v. Shalala, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998).

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[*32]

Judge Gajarsa's reasoning addresses the practical difficulties facing a generic in plaintiffs' situation, i.e., a generic who does not face a "reasonable apprehension of suit" but who needs a judicial determination in order to get to market. Nevertheless, absent binding precedent or further edification through legislation, the court declines to extend the well established principles governing declaratory judgment actions to cover the admittedly frustrating position occupied by plaintiffs at bar. In the first instance, defendants were required by statute to list the '450 patent in the Orange Book. In light of this obligation, the court is not convinced that defendants intended to communicate an intent to sue each and every generic who opts to file an ANDA for *quinapril hydrochloride*, contrary to plaintiffs' suggestion. The evidence of record, in fact, shows an opposite intention. To date, defendants have asserted the '450 patent only against Teva, despite at least eight other generics having filed ANDAs for *quinapril hydrochloride* with paragraph IV certifications. Additionally, our sister courts, when confronted with virtually identical facts to those at bar, have found that [*33] [HN19]the act of listing a patent in the Orange Book does not create an "actual controversy." See Mutual Pharm. v. Pfizer, 307 F. Supp.2d 88 (D. D.C. 2004); Dr. Reddys Labs., Ltd. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 24351, 2004 WL 596106 (D. N.J. 2003); Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940, 69 U.S.P.Q.2d 1791 (D. Mass. 2003). Indeed, the District of Massachusetts has noted that "[a] blanket reference to this effect would cover every patent holder who listed a patent, thereby eliminating the second prong of the test. A patent holder may have reasons to sue for infringement, and all things depending, reasons not to sue." 2003 U.S. Dist. LEXIS 21940, [WL] at *13. The court, consequently, concludes that the mere listing of a patent in the Orange Book does not give plaintiffs reason to fear suit.

Plaintiffs also point out that defendants failed to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent and failed to provide them with a covenant not to sue. While the Federal Circuit previously has acknowledged that a patent holder's failure to give such an assurance is relevant to a court's jurisdictional inquiry, BP Chems. Ltd. 4 F.3d at 980. [*34]

plaintiffs fail to cite evidence to demonstrate that they requested either an assurance or a covenant not to sue. Moreover, even if plaintiffs made such requests, defendants are not required under the Hatch-Waxman Act to give either an assurance or a covenant not to sue. Thus, the court declines to construe defendants' silence as conduct sufficient to suggest an intention to sue.

Plaintiffs likewise maintain that defendants' litigation history establishes a reasonable apprehension of suit. In this regard, plaintiffs call attention to fact that defendants: (1) are engaged in an ongoing infringement action against Teva regarding the '450 patent; (2) have been involved in suits against plaintiffs and at least eight other ANDA filers over Neurotin(R) for the past five years; and (3) are actively pursuing other infringement actions against various generics who sought to market generic versions of their brand drugs, including Zoloft(R), Celebrex(R), Lipitor(R), Norvasc(R), Procardia XL(R), Glucotrol XL(R), and Xalatan(R). As to plaintiffs' litigation involving the '450 patent, defendants have not sued any of the subsequent eight ANDA filers, four of whom filed ANDAs prior to plaintiffs. **[*35]** n14 Contrary to plaintiffs' characterization of this fact as "meaningless," the court finds it to be persuasive evidence that defendants are not engaged in a pattern of widespread litigation aimed at enforcing the '450 patent against all generics interested in marketing generic *quinapril hydrochloride*. As such, the court declines to conclude that defendants' litigation efforts with respect to Teva translate into an intent to enforce the '450 patent against plaintiffs.

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n14 Geneva Pharmaceuticals, Andrx Pharmaceuticals, Par Pharmaceuticals, Inc., and Ivax Pharmaceuticals, Inc. filed ANDAs seeking approval to market generic *quinapril hydrochloride* on January 9, 2001, January 25, 2001, June 1, 2001, and July 20, 2001, respectively. Plaintiffs did not file their ANDA until September 13, 2001.

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The court is equally unpersuaded that defendants' Neurotin(R) litigation created a reasonable apprehension of suit. In Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987), **[*36]** the Federal Circuit acknowledged that a history of adverse legal interests bears upon the reasonable apprehension issue, even if the prior litigation did not involve the same patents implicated in the declaratory judgment suit. Nonetheless, the court observes that the link between the parties' adverse legal interests in Goodyear were much stronger than those at bar. In Goodyear, the defendant sued the plaintiff in state court over the same technology covered by the patents disputed in the declaratory judgment action. The Federal Circuit opined that, "by suing Goodyear in state court for the same technology as is now covered by the patents, [defendant] has engaged in a course of conduct that shows a willingness to protect that technology." Id. at 956. In contrast, defendants' Neurotin(R) litigation does not implicate the same technology as would be involved in a suit over Accupril(R). Therefore, the court finds that defendants' desire to protect their presence in the pain and seizure markets with Neurotin(R) is unrelated to their intentions as to the hypertension and heart failure markets with Accupril(R). While the parties' adverse interests remain a consideration, **[*37]** the court finds that the factual background in this case, unlike the factual background in Goodyear, is not such that plaintiffs had an objective reason to fear litigation.

Similarly, the court finds that defendants' litigation against third party generics, even when viewed in the aggregate with defendants' suit against Teva and their Neurotin(R) litigation, does not place plaintiffs in a reasonable apprehension of suit. (See D.I. 27, ex. B) Plaintiffs overdramatize the situation in stating "there is no end to the lengths that [defendants] will go to protect its branded monopolies through litigation." Plaintiffs' subjective beliefs do not amount to a threat or other action sufficient to prove the imminence of a lawsuit. In addition, that defendants enforced their patent rights against other generics with respect to Zoloft(R), Celebrex(R), Lipitor(R), Norvasc(R), Procardia XL(R), Glucotrol XL(R), and Xalatan(R) does not provide any indication of its intentions regarding the '450 patent and *quinapril hydrochloride*. To this end, the Federal Circuit considers whether the parties have engaged in some form of communication about the patent in dispute when analyzing the reasonable **[*38]** apprehension question. n15

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n15 Notably, the Federal Circuit also has recognized that "if circumstances warrant, a reasonable apprehension may be found in the absence of any communication from defendant to plaintiff." Arrowhead, 846 F.2d at 736.

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[HN20]

The Federal Circuit has cautioned:

> The test for finding a "controversy" for jurisdictional purposes is a pragmatic one and cannot turn on whether the parties use polite terms in dealing with one another or engage in more bellicose saber rattling. The need to look to substance rather than form is especially important in this area, because in many instances ... the parties are sensitive to the prospect of a declaratory judgment action and couch their exchanges in terms designed either to create or defeat declaratory judgment jurisdiction. In the end, the question is whether the relationship between the parties can be considered a "controversy," and that inquiry does not turn on whether the parties have used particular "magic words" in communicating **[*39]** with one another.

EMC Corp., 89 F.3d at 811-12. The Federal Circuit has found no apprehension of suit existed where the patent holder has made no contact with the declaratory judgment plaintiff. West Interactive Corp. v. First Data Res., Inc., 972 F.2d 1295, 1297 (Fed. Cir. 1992). n16 In the case at bar, plaintiffs have not alleged any communication, either direct or indirect, from defendants concerning the '450 patent. The record also does not reveal any such communication. Moreover, the record does not show that defendants communicated with any third parties about plaintiffs or the '450 patent. As noted above, defendants have stood silent throughout the course of this litigation. The only interaction between the parties, in fact, occurred when plaintiffs initiated contact with defendants by: (1) notifying them of their ANDA with paragraph IV certification as required by 21 U.S.C. § 355 (j) (2) (B); and (2) sending them a letter offering confidential access to their ANDA in accordance with 21 U.S.C. § 355 (j) (5) (C) (i) (I) (2). Given these circumstances, plaintiffs cannot complain that they feared **[*40]** that defendants would sue them for patent infringement.

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n16 In contrast, the Federal Circuit has held the reasonable apprehension inquiry satisfied in certain situations where the defendant directly communicated with the plaintiff. See, e.g., Sierra Applied Scis. Inc. v. Advanced Energy Indus., 363 F.3d 1361, 1374 (Fed. Cir. 2004) (concluding that letters from defendant to plaintiff expressly charging plaintiff with patent infringement were sufficient to establish a reasonable apprehension); EMC Corp., 89 F.3d at 812 (finding a letter from defendant to plaintiff referencing "'turning the matter over to'" plaintiff's litigation counsel '" for action'" and urging a "'preliminary business discussion,'" "'perhaps avoiding this matter escalating into a contentious legal activity[,]'" to be the "most telling evidence" of reasonable apprehension).

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Finally, defendants' press release statement that they "will continue aggressively to defend challenges to [their] intellectual property" **[*41]** is not sufficient to instill a reasonable apprehension of suit. Defendants' statement, even though made in the context of discussing the infringement suit against Teva, is of a general nature, directed to their overall strategy of enforcing their patent rights against generic competition. It is not specifically directed against plaintiffs, nor is there any evidence suggesting that it was made with plaintiffs in mind. The Federal Circuit has held that [HN21]a patent holder's statement that it intends to enforce its patent does not create a reasonable apprehension of suit. Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1054 (Fed. Cir. 1995) (discussing Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 889 (Fed. Cir. 1992)). Accordingly, the court concludes that, under the totality of the circumstances, defendants did not engage in conduct sufficient to give plaintiffs a reasonable apprehension of suit at the time they filed the complaint at bar. The court, therefore, grants defendants' motions to dismiss for lack of subject matter jurisdiction. n17

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n17 As noted above, the court is sympathetic to plaintiffs' situation. Plaintiffs must dwell within the frustrating Hatch-Waxman "bottleneck" (the expiration of Teva's 180-day period of exclusivity) before marketing their generic version of *quinapril* hydrochloride. The start of this exclusivity period presently, however, remains unknown and will not be triggered until either: (1) Teva voluntarily

markets its generic *quinapril hydrochloride,* which it is not likely to do given the District of New Jersey's finding of infringement; (2) the District of New Jersey decides the issues of validity and enforceability of the '450 patent; or (3) another court declares the '450 patent invalid. Thus, subsequent ANDA filers, like plaintiffs, are placed in a conundrum when attempting to market their generic versions of brand drugs under the current regulatory framework.

---------- End Footnotes- - - - - - - - - - - - - -

[*42]

V. CONCLUSION

For the reasons stated, the court grants defendants' motions to dismiss for lack of subject matter jurisdiction. An order shall issue.

ORDER

At Wilmington this 28th day of June, 2004, consistent with the opinion issued this same date;

IT IS ORDERED that defendants' motions to dismiss (D.I. 8, 20) are granted.

Sue L. Robinson

United States District Judge

APOTEX, INC. and APOTEX CORP., Plaintiffs, - against - PFIZER INC., Defendant.

04 Civ. 2539 (DC)

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

2004 U.S. Dist. LEXIS 26232

December 30, 2004, Decided
January 3, 2005, Filed

DISPOSITION-1: [*1] Defendant's motion to dismiss for lack of subject matter jurisdiction was granted.

CASE SUMMARY

PROCEDURAL POSTURE: In a patent case, plaintiffs brought a declaratory judgment action for a determination that their generic drug did not infringe a patent held by defendant. Defendant moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy between the parties.

OVERVIEW: Although plaintiffs asked the court to disregard the reasonable apprehension test, and, instead to employ the U.S. Const. art. III case or controversy analysis applied in non-patent cases and in patent cases involving allegations of actual (as opposed to potential) infringement, the argument was rejected and the two-prong reasonable apprehension test was applied. Defendant did not dispute that the second prong of the reasonable apprehension test was met. By filing the Abbreviated New Drug Application (ANDA), plaintiffs committed a defined act of infringement sufficient to create case or controversy jurisdiction in patent infringement actions. However, plaintiffs did not show that defendant created a reasonable apprehension of patent litigation, and thus no actual controversy existed. Defendant's listing of the patent in the "Orange Book"--the Approved Drug Products With Therapeutic Equivalence Evaluations--and defendant's suit against another entity did not contribute to a reasonable apprehension of suit; defendant's history of litigation, though lengthy, was not sufficiently related to this case to create a reasonable apprehension of suit.

OUTCOME: Defendant's motion to dismiss for lack of subject matter jurisdiction was granted.

CORE TERMS: patent, apprehension, subject matter jurisdiction, Medicare Amendments, declaratory judgment, certification, patent infringement, infringement, listing, filer, brand name, hydrochloride, exclusivity, setraline, pioneer, generic drug, manufacturer, forty-five, marketing, infringed, invalid, generic, actual controversy, threatening, expire, prong, Declaratory Judgment Act, declaratory judgment action, motion to dismiss, expiration

LexisNexis(TM) Headnotes

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN1]Under the Hatch-Waxman Amendments, companies that want to market generic versions of pioneer drugs may file with the Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA), relying on the FDA's prior determinations that the pioneer drug was safe and effective. 21 U.S.C.S. § 355(j)(2)(A).

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN2]A pioneer drug manufacturer is required to notify the Food and Drug Administration (FDA) of all patents that cover the pioneer drug. 21 U.S.C.S. § 355(b)(1), (c)(2). These patents and their expiration dates are listed by the FDA in what is commonly known as the "Orange Book"--the Approved Drug Products With Therapeutic Equivalence Evaluations. For all applicable patents listed in the Orange Book, Abbreviated New Drug Application (ANDA) applicants must certify whether the generic drug would infringe the patents. 21 U.S.C.S. § 355(j)(2)(A)(vii). Specifically, the ANDA applicant may certify that (I) the required patent information has not been submitted to the FDA; (II) the patent has expired; (III) the patent has not expired but is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the new generic drug for which the ANDA is submitted. 21 U.S.C.S. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN3]If an Abbreviated New Drug Application (ANDA) applicant makes a paragraph IV (21 U.S.C.S.

§ 355(j)(2)(A)(vii)(IV)) certification and the patent holder (the pioneer drug company) sues for patent infringement within forty-five days, the Food and Drug Administration (FDA) may not approve the ANDA until expiration of the patent, a judicial determination that the patent is invalid or not infringed, or thirty months, whichever is earlier. If the patentee does not sue, the ANDA will be approved. 21 U.S.C.S. § 355(j)(2)(B)(I), (5)(B)(iii); 21 C.F.R. § 314.95(c)(6). The first applicant to file an ANDA with a paragraph IV certification is a "first filer," and is eligible for a 180-day exclusivity period during which it is entitled to have the sole generic version of the pioneer drug on the market. 21 U.S.C.S. § 355(j)(5)(B)(iv). The FDA is prohibited from approving any other ANDA involving the same brand name drug until the end of the exclusivity period, i.e., during that period only the brand name manufacturer and the first filer may market that drug. The marketing exclusivity period does not begin immediately upon FDA approval of the first ANDA, but rather upon the earlier of (1) the first commercial marketing of the drug, or (2) the date of a court decision declaring the patent invalid or not infringed.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN4]The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) established forfeiture provisions to prevent bottlenecking and revised sections of the patent code authorizing declaratory judgment actions by Abbreviated New Drug Application (ANDA) filers. In particular, Congress provided that the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any declaratory judgment action by a generic manufacturer who (1) has filed an ANDA with a paragraph IV (21 U.S.C.S. § 355(j)(2)(A)(vii)(IV)) certification and (2) was not sued by the NDA holder within the forty-five day statutory period. 35 U.S.C.S. § 271(e)(5).

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Jurisdiction Over Action

Civil Procedure > Pleading & Practice > Defenses, Objections & Demurrers > Motions to Dismiss

[HN5]In considering a motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), federal courts need not accept as true contested jurisdictional allegations. Rather, a court may resolve disputed jurisdictional facts by referring to evidence outside the pleadings. The party seeking to invoke the subject matter jurisdiction of the district court bears the burden of demonstrating that there is subject matter jurisdiction.

Civil Procedure > Remedies > Declaratory Relief

[HN6]Subject matter jurisdiction under the Declaratory Judgment Act requires the existence of an actual case or controversy: The Declaratory Judgment Act permits declaratory relief only in cases presenting actual controversies, a requirement that incorporates into the statute the case or controversy limitation on federal jurisdiction found in U.S. Const. art. III.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

Patent Law > Remedies > Declaratory Relief

[HN7]In declaratory judgment actions for patent invalidity or non-infringement, the courts have applied a two-part test to determine whether an "actual controversy" exists: There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity. The first prong of this inquiry examines the defendant's conduct, while the second prong focuses on the plaintiff's conduct. This two-part test has become known as the "reasonable apprehension" test.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

Patent Law > Remedies > Declaratory Relief

[HN8]To determine whether there is a reasonable apprehension that the defendant will sue for patent infringement, courts apply an objective test that focuses on the conduct of the defendant and attempts to ascertain whether a defendant has shown an intent to enforce its patent rights. Such an intent is readily exhibited with express accusations of infringement and threats to bring suit. Explicit threats, however, are not required to create a reasonable apprehension. In light of the subtleties in lawyer language the courts have not required an express infringement charge, finding instead that reasonable apprehension may be induced by subtler conduct. In the absence of overt threats, the "totality of the circumstances" must be considered in evaluating whether a reasonable apprehension of infringement litigation exists. In other words, the court must look at the full range of the defendant's conduct and determine whether those actions, considered in context, create a reasonable apprehension.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

Patent Law > Remedies > Declaratory Relief

[HN9]The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) do not disturb the Federal Circuit's consistent holding that the constitutional limits of a U.S. Const. art. III court's jurisdiction in anticipatory patent infringement declaratory judgment actions are defined by the two-part reasonable apprehension test.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN10]According to the plain language of the law, an "Orange Book"--the Approved Drug Products With Therapeutic Equivalence Evaluations--listing represents merely that, in certain circumstances, an infringement claim "could" be asserted, but not that one will be asserted. 21 U.S.C.S. § 355(b)(1). An Orange Book listing imposes no obligation on the patent owner to sue, and does not suggest that a suit is expected or even likely. An Orange Book listing is unlike a private letter and does not carry the same threatening suggestion. An Orange Book listing is directed to the Food and Drug Administration, not any company in particular, and is submitted as a necessary element of the drug application. 21 U.S.C.S. § 355(a), (b)(1).

COUNSEL: For Plaintiffs: William A. Rakoczy, Esq., Deanne M. Mazzochi, Esq., Amy D. Brody, Esq., RAKOCZY MOLINO MAZZOCHI SIWIK LLP, Chicago, Illinois.

For Defendant: Dimitrios T. Drivas, Esq., Jeffrey J. Oelke, Esq., Brendan G. Woodward, Esq., WHITE & CASE LLP, New York, New York.

JUDGES: DENNY CHIN, United States District Judge.

OPINIONBY: DENNY CHIN

OPINION: MEMORANDUM DECISION

CHIN, D.J.

In this patent case, plaintiffs Apotex, Inc. and Apotex Corp. (together, "Apotex") bring a declaratory judgment action for a determination that their generic drug does not infringe U.S. Patent No. 5,248,699 ("the '699 patent"), held by defendant Pfizer Inc. ("Pfizer"). Pfizer moves to dismiss the action, arguing that the Court lacks subject matter jurisdiction because of the absence of an actual controversy between the parties. For the reasons that follow, the motion is granted and the complaint is dismissed, without prejudice.

BACKGROUND

A. Regulatory Background

1. Hatch-Waxman Amendments

This dispute arises under a series of amendments to the Federal Food, Drug, and Cosmetic [*2] Act of 1938 (the "FDCA"), 21 U.S.C. § 1 et seq. The "Hatch-Waxman Amendments," enacted as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), simplified Food and Drug Administration ("FDA") procedures for the approval of generic drugs. Mova Pharm. Corp. v. Shalala, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1063 (D.C. Cir. 1998). [HN1]Under the Hatch-Waxman Amendments, companies that want to market generic versions of pioneer drugs may file with the FDA an Abbreviated New Drug Application ("ANDA"), relying on the FDA's prior determinations that the pioneer drug was safe and effective. See 21 U.S.C. § 355(j)(2)(A); see generally Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002); Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1325-27 (Fed. Cir. 2001); Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd., 325 F. Supp. 2d 502 (D.N.J. 2004).

[HN2]A pioneer drug manufacturer is required to notify the FDA of all patents that cover the pioneer drug. 21 U.S.C. § 355(b)(1), (c)(2). These patents and their expiration [*3] dates are listed by the FDA in what is commonly known as the "Orange Book" -- the "Approved Drug Products With Therapeutic Equivalence Evaluations." For all applicable patents listed in the Orange Book, ANDA applicants must certify whether the generic drug would infringe the patents. 21 U.S.C. § 355(j)(2)(A)(vii). Specifically, the ANDA applicant may certify that (I) the required patent information has not been submitted to the FDA; (II) the patent has expired; (III) the patent has not expired but is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications. See generally Andrx Pharms., Inc., 276 F.3d at 1371.

[HN3]If an ANDA applicant makes a paragraph IV certification and the patent holder (the pioneer drug company) sues for patent infringement within forty-five days, the FDA may not approve the ANDA until expiration of the patent, a judicial determination that the patent is invalid or not infringed, or thirty months, whichever [*4] is earlier. If the patentee does not sue, the ANDA will be approved. 21 U.S.C. § 355(j)(2)(B)(I), (5)(B)(iii); 21 C.F.R. § 314.95(c)(6).

The first applicant to file an ANDA with a paragraph IV certification is a "first filer," and is eligible for a 180-day exclusivity period during which it is entitled to have the sole generic version of the pioneer drug on the market. 21 U.S.C. § 355(j)(5)(B)(iv). The FDA is prohibited from approving any other ANDA involving the same brand name drug until the end of the exclusivity period, i.e., during that period only the brand name manufacturer and the first filer may market that drug. Id. The marketing exclusivity period does not begin immediately upon FDA approval of the first ANDA, but rather upon the earlier of (1) the first commercial marketing of the drug, or (2) the date of a court decision declaring the patent invalid or not infringed. Id.

While the Hatch-Waxman framework "has saved billions and billions of dollars for consumers[,] . . . there [has been] a gaming of the system" by some brand name drug companies. 149 Cong. Rec. S15563 (daily ed. Nov. 22, 2003) (statement of [*5] Sen. Hatch); see Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," 27-31 (July 1998). Some brand name drug manufacturers have succeeded in "parking" the 180-day marketing exclusivity period, indefinitely delaying ANDA approvals and bottlenecking the market. Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," vi-vii (July 2002). "Parking" occurs when the brand name manufacturer convinces the first filer not to enter the market, often through a settlement agreement concluding a patent infringement suit. Id. Absent an intervening court decision, the first filer's failure to enter the market delays the triggering of the 180-day exclusivity period so that it neither begins nor ends, and subsequently filed ANDAs cannot be approved. Id.

2. Medicare Amendments

To curb these abuses, Congress added another round of amendments to the FDCA in the comprehensive Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Amendments"). Pub. L. No. 108-173, 117 Stat. 2066 (2003). [HN4]The Medicare Amendments established forfeiture provisions [*6] to prevent bottlenecking and revised sections of the patent code authorizing declaratory judgment actions by ANDA filers. Id. In particular, Congress provided that "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction" in any declaratory judgment action by a generic manufacturer who (1) has filed an ANDA with a paragraph IV certification and (2) was not sued by the NDA holder within the forty-five day statutory period. 35 U.S.C. § 271(e)(5).

B. Facts

1. Pfizer

Pfizer markets Zoloft(R), the brand name version of setraline hydrochloride approved by the FDA for the treatment of mood and anxiety disorders. Pfizer has listed Zoloft(R) in the Orange Book, associating it with the '699 patent and U.S. Patent No. 4,356,518 ("the '518 patent"). The '699 patent will expire on September 28, 2010, and the '518 patent will expire on June 30, 2006.

2. IVAX

In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as IVAX, filed the first setraline hydrochloride ANDA. IVAX submitted a paragraph IV certification with respect to the '699 patent, i.e., it asserted that [*7] the '699 patent was invalid or not infringed by IVAX's product, and a paragraph III certification with respect to the '518 patent, i.e., it asserted that IVAX will not enter the market until the expiration of the '518 patent on June 30, 2006. As the first filer, IVAX was entitled to a 180-day marketing exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv). Pfizer responded within forty-five days of receiving notice of the ANDA, initiating a patent infringement action against IVAX in January 2000. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the suit automatically suspended FDA approval of the IVAX ANDA for thirty months. The parties reached a settlement in May 2002 that provided that IVAX would receive a license to the '699 patent and may begin marketing setraline hydrochloride by June 30, 2006.

3. Apotex

On October 27, 2003, Apotex filed an ANDA seeking the FDA's approval to market its version of setraline hydrochloride. Like IVAX, Apotex filed a paragraph III certification with respect to the '518 patent and a paragraph IV certification with respect to the '699 patent. Pursuant to the Hatch-Waxman framework, the FDA [*8] cannot approve the Apotex ANDA until 180 days after IVAX enters the market or a court decision decrees the '699 patent invalid or not infringed, whichever is earlier. If neither event occurs, the Apotex ANDA cannot be approved until September 2010, when the last Zoloft-related patent expires. See 21 U.S.C. § 355(j)(5)(B)(ii).

4. Other ANDA Filers

In addition to IVAX and Apotex, at least six other generic drug manufacturers have filed ANDAs for

setraline hydrochloride; Pfizer has initiated suit against none of them. (Myers Decl. P9). Two of these companies, Teva Pharmaceuticals USA, Inc. and Dr. Reddy's Laboratories, Ltd., filed ANDA-related declaratory judgment actions against Pfizer, as Apotex has done here. (Def.'s Mem. at 7-8). Both cases were dismissed for lack of subject matter jurisdiction. Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940, No. 03-CV-10167 (RGS), 2003 WL 22888848, at *1 (D. Mass. Dec. 8, 2003); Dr. Reddys Labs., Ltd. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 24351, No. 03-CV-726 (JAP), 2003 WL 21638254, at *7 (D.N.J. July 8, 2003).

C. Procedural History

Apotex filed its complaint on April 1, 2004. On June 22, 2004, Pfizer **[*9]** moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. Pfizer argues that this Court does not have subject matter jurisdiction because of the absence of an actual controversy, as required by the Declaratory Judgment Act. 28 U.S.C. § 2201(a). Apotex contends that there is such a controversy. For the reasons that follow, the motion to dismiss is granted.

DISCUSSION

A. Applicable Law

1. Motion to Dismiss Standard

[HN5]In considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), federal courts "need not accept as true contested jurisdictional allegations." Jarvis v. Cardillo, 1999 U.S. Dist. LEXIS 4310, No. 98 Civ. 5793 (RWS), 1999 WL 187205, at *2 (S.D.N.Y. Apr. 5, 1999). Rather, a court may resolve disputed jurisdictional facts by referring to evidence outside the pleadings. Zappia Middle E. Constr. Co. v. Emirate of Abu Dhabi, 215 F.3d 247, 253 (2d Cir. 2000); Filetech S.A. v. France Telecom S.A., 157 F.3d 922, 932 (2d Cir. 1998). As the party "seeking to invoke the subject matter jurisdiction of the district court," plaintiff bears **[*10]** the burden of demonstrating that there is subject matter jurisdiction in this case. Scelsa v. City Univ. of New York, 76 F.3d 37, 40 (2d Cir. 1996).

2. Subject Matter Jurisdiction

[HN6]Subject matter jurisdiction under the Declaratory Judgment Act requires the existence of an actual case or controversy: "The Declaratory Judgment Act permits declaratory relief only in cases presenting 'actual controversies,' . . . a requirement that incorporates into the statute the case or controversy limitation on federal jurisdiction found in Article III of the Constitution." Niagara Mohawk Power Corp. v. Tonawanda Band of Seneca Indians, 94 F.3d 747, 752 (2d Cir. 1996) (citing 28 U.S.C. § 2201(a)).

3. The Reasonable Apprehension Test

[HN7]In declaratory judgment actions for patent invalidity or non-infringement, the courts have applied a two-part test to determine whether an "actual controversy" exists:

> There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity **[*11]** which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Fina Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1481 (Fed. Cir. 1998). The first prong of this inquiry examines the defendant's conduct, while the second prong focuses on the plaintiff's conduct. Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 736 (Fed. Cir. 1988). This two-part test has become known as the "reasonable apprehension" test.

[HN8]To determine whether there is a reasonable apprehension that the defendant will sue for patent infringement, courts apply an objective test that focuses on the conduct of the defendant and attempts to ascertain whether a defendant has shown an intent to enforce its patent rights. Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 888 (Fed. Cir. 1992); Arrowhead, 846 F.2d at 736. Such an intent is readily exhibited with express accusations of infringement and threats to bring suit. Explicit threats, however, are not required to create a reasonable apprehension. EMC Corp. v. Norand Corp., 89 F.3d 807, 811 (Fed. Cir. 1997). "In light of the subtleties **[*12]** in lawyer language . . . the courts have not required an express infringement charge," Arrowhead, 846 F.2d at 736, finding instead that "reasonable apprehension. . . may be induced by subtler conduct." EMC Corp., 89 F.3d at 811.

In the absence of overt threats, the "totality of the circumstances" must be considered in evaluating whether a reasonable apprehension of infringement litigation exists. Arrowhead, 846 F.2d at 736. In other words, the court must look at the full range of the defendant's conduct and determine whether those actions, considered in context, create a reasonable apprehension. Consac Indus. v. Nutramax Lab., 1998 U.S. Dist. LEXIS 6228, No. 97 Civ. 1155 (SJ), 1998 WL 229255, at *3 (E.D.N.Y. Mar. 31, 1998).

4. The Medicare Amendments

Apotex argues that the reasonable apprehension test is "legally irrelevant," contending that it no longer applies because of the Medicare Amendments passed in 2003. (Pl.'s Mem. at 7). Instead, Apotex argues, the Medicare Amendments expressly authorize an ANDA-filer to bring a declaratory judgment action where, as here, a patentee does not file suit within the forty-five **[*13]** day period. (Id. at 8 (citing 21 U.S.C. § 355(j)(5)(C)). It also relies on the amendment to the patent code, which provides that federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over declaratory judgment actions for a declaration of invalidity or non-infringement brought by ANDA applicants who have made a paragraph IV certification. (Id.).

Accordingly, Apotex asks the Court to disregard the reasonable apprehension test, and, instead to employ the Article III case or controversy analysis applied in non-patent cases and in patent cases involving allegations of actual (as opposed to potential) infringement, requiring that "there is (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision." (Pls.' Mem. at 12 (citing Bennett v. Spear, 520 U.S. 154, 162, 167, 137 L. Ed. 2d 281, 117 S. Ct. 1154 (1997); Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240-41, 81 L. Ed. 617, 57 S. Ct. 461 (1937); and Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1331 (Fed. Cir. 2003)). Apotex argues that the changes made by the Medicare Amendments require **[*14]** a similar analysis for ANDA-related declaratory judgment actions.

The argument is rejected. [HN9]The Medicare Amendments do not disturb the Federal Circuit's consistent holding that the constitutional limits of an Article III court's jurisdiction in anticipatory patent infringement declaratory judgment actions are defined by the two-part reasonable apprehension test. Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361 (Fed. Cir. 2004); Arrowhead, 846 F.2d at 736; TorPharm, Inc. v. Pfizer, Inc., 2004 U.S. Dist. LEXIS 11930, No. Civ. 03-990-SLR, 2004 WL 1465756, at *7 (D. Del. June 28, 2004) (citing Medicare Amendments and holding reasonable apprehension test is "'consistent with the Constitution'"); Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd., 325 F. Supp. 2d 502, 507-08 (D.N.J. 2004). All of these decisions post-date the Medicare Amendments.

The legislative history of the Medicare Amendments supports the continued application of the reasonable apprehension test. The Conference Report accompanying the Medicare Amendments explains plainly, "the conferees do not intend for the courts to modify their application of the requirements **[*15]** under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction." H.R. Conf. Rep. No. 108-391, at 836 (2003). In response, Apotex points to Congressional testimony reflecting a general intent to eliminate ANDA bottlenecks, arguing that jurisdiction in this case would effectuate that goal. (Pls.' Mem. at 9). While that may be true, it does not show that Congress intended to replace the well-established reasonable apprehension test for declaratory judgment patent cases with the analysis used in non-patent cases.

Accordingly, I apply the two-prong reasonable apprehension test.

B. Application

Pfizer does not dispute that the second prong of the reasonable apprehension test has been met. (See Def.'s Mem. at 10-20). By filing the ANDA, Apotex--committed a "defined act of infringement sufficient to create case or controversy jurisdiction" in patent infringement actions. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). Therefore I address only the first prong -- whether Pfizer's conduct gave rise to a reasonable apprehension **[*16]** of suit.

Apotex has not shown that Pfizer created a reasonable apprehension of patent litigation, and thus no actual controversy exists. Therefore this Court does not have subject matter jurisdiction. The Court notes that two District Courts recently reached the same conclusion, in virtually identical cases involving the same patents and products at issue here. Teva Pharms. USA, Inc. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 21940, No. 03-CV-10167 (RGS), 2003 WL 22888848 (D. Mass. Dec. 8, 2003); Dr. Reddy's Labs., Ltd. v. Pfizer Inc., 2003 U.S. Dist. LEXIS 24351, No. 03-CV-726 (JAP), 2003 WL 21638254 (D.N.J. July 8, 2003). Likewise, courts in three other similar declaratory judgment cases also dismissed for lack of subject matter jurisdiction. TorPharm, Inc. v. Pfizer Inc., 2004 U.S. Dist. LEXIS 11930, No. Civ. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004); Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd., 325 F. Supp. 2d 502 (D.N.J. 2004). Mutual Pharm. Co. v. Pfizer Inc., 307 F. Supp. 2d 88 (D.D.C. 2004).

As Pfizer has not explicitly threatened suit (Def.'s Mem. at 15), I consider the totality of the circumstances. See Arrowhead, 846 F.2d at 736. Apotex identifies four **[*17]** aspects of Pfizer's conduct that, taken together, allegedly give rise to a reasonable apprehension of suit: (1) Pfizer listed the '699 patent in the Orange Book, (2) Pfizer asserted the

'699 patent against IVAX, (3) Pfizer has a history of litigating its patents, and (4) Pfizer has not acknowledged that Apotex's product does not infringe the '699 patent. (Pls.' Mem. at 21-25).

First, Pfizer's listing of the '699 patent in the Orange Book does not contribute to a reasonable apprehension of suit. [HN10]According to the plain language of the law, an Orange Book listing represents merely that, in certain circumstances, an infringement claim "could" be asserted, but not that one will be asserted. 21 U.S.C. § 355(b)(1). An Orange Book listing imposes no obligation on the patent owner to sue, and does not suggest that a suit is expected or even likely. Id.; see TorPharm, Inc., 2004 U.S. Dist. LEXIS 11930, 2004 WL 1465756, at *9 (finding that an Orange Book listing does not "communicate an intent to sue each and every generic who opts to file an ANDA"). Apotex compares the Orange Book listing to a private letter, noting that reasonable apprehension would exist if Pfizer had sent a letter **[*18]** to Apotex bearing the very same message. (Pls.' Mem. at 22). An Orange Book listing is unlike a private letter and does not carry the same threatening suggestion. An Orange Book listing is directed to the FDA, not any company in particular, and is submitted as a necessary element of the drug application. See 21 U.S.C. § 355(a), (b)(1).

Second, Pfizer's suit against IVAX does not contribute to a reasonable apprehension of suit. There was a distinct statutory incentive for Pfizer to sue IVAX: by suing the first filer within forty-five days of notice of the ANDA, Pfizer received an automatic thirty-month delay in the approval of that ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). There is no similar incentive for suing Apotex. Moreover, Pfizer has not sued any of the other ANDA applicants. (Myers Decl. P9).

Third, Pfizer's history of litigation, though lengthy, is not sufficiently related to this case to create a reasonable apprehension of suit. In cases where courts have found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, Arrowhead, 846 F.2d at 733; **[*19]** Ivoclar Vivadent, Inc. v. Hasel, 2003 U.S. Dist. LEXIS 12611, No. 02-CV-0316E(F), 2003 WL 21730520, at *1 (W.D.N.Y. June 30, 2003), or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology. Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953 (Fed. Cir. 1987); Clontech Lab., Inc. v. Life Techs., Inc., 2000 U.S. Dist. LEXIS 19320, No. Civ.A. AW-00-1879, 2000 WL 33124811, at *1 (D. Md. Dec. 20, 2000); SmithKline Beech Am Corp. v. Zenith Goldline Pharms., Inc., 2000 U.S. Dist. LEXIS 9659, No. Civ.A. 00-CV-1393, 2000 WL 963165, at *1 (E.D. Pa. June 28, 2000). Apotex does not claim that Pfizer sent any threatening communication, but rather it relies on the fact that Pfizer has previously asserted its patent rights against other generic drug companies. (Pls.' Mem. at 24). What is missing from Apotex's argument, however, is an explanation as to how setraline hydrochloride is "essentially the same technology involved" in those actions. See Goodyear Tire, 824 F.2d at 954. Companies that profit largely from research and development will frequently find themselves involved in patent infringement litigation; what creates **[*20]** a reasonable apprehension of suit in any given case is a relationship between that case and some prior litigation. Apotex has not established such a relation here.

Finally, Apotex asks the Court to consider Pfizer's refusal to acknowledge non-infringement, but Apotex does not explain how this behavior is threatening. (Pls.' Mem. at 25). At most, Pfizer's refusal is ambiguous; it does not affirmatively show an intent to sue.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss for lack of subject matter jurisdiction is granted. The Clerk of the Court shall enter judgment dismissing the complaint without prejudice and close this case.

SO ORDERED.

Dated: New York, New York

December 30, 2004

DENNY CHIN

United States District Judge